Safety Data Sheet

According to Regulation (EU) 2015/830

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 Chrome Alginate Fast Set Chromatic

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	(SU21) Consumer Uses: Private households (=general public = consumers);
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)

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

2.2 Label Elements

Hazard Pictograms	
Signal Word	Warning
Hazard Statement	Eye Irrit. 2: H319 – Causes serious eye irritation. STOT RE 2: H373 - Causes damage to organs through prolonged or repeated exposure (lungs via inhalation)
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	P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing P337+P313 – If eye irritation persists: Get medical advice/attention

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%

Further information

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

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
Kieselguhr, soda ash flux-calcined	01-211-9488518-22	68855-54-9	272-489-0		65.0-80.0	STOT RE 2:H373
Dipotassium hexafluorotitanate	01-2119978268-20-0006	16919-27-0	240-969-9		1.0-2.5	Acute Tox. 4:H302 Eye Dam. 1:H318

Kieselguhr, soda ash flux calcined:

STOT-REPEATED EXPOSURE: the substance is classified in this hazard class because it contains respirable crystalline silica (cristobalite, CAS 14464-46-1), classified as STOT RE 1, as impurity contained in quantity from 1 to 10%.

Note: Upper limit is not included into the range.

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

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.

This product may cause functional disorders or morphological mutations after repeated or prolonged exposure and/or may accumulate inside the human body and is thus graded as dangerous.

Acute effects: stinging eyes. Symptoms may include: rubescence, edema, pain and lachrymation. Ingestion may cause health problems, including stomach pain and sting, nausea and sickness

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).

5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

	The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray

5.2 Special hazards arising from the substance or mixture

	Do not breathe combustion products

5.3 Advice for firefighters

	Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always water 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. 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).

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 or both processing staff and those involved in emergency procedures.

6.2 Environmental precautions

	This product must not penetrate into the sewer system or come in to contact with surface water or ground water.

6.3 Methods and material for containment and cleaning up

	Use spark-proof mechanical equipment to collect the leaked product and place it in containers for recover or disposal. If there are no contraindications, use jets of water to eliminate residues. 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.

6.4 Reference to other sections

	See section 13 for disposal information. See section 8 for exposure controls/personal protection.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

	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.

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.

7.3 Specific end use(S)

	No use other than specified in Section 1.2 of this SDS.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Exposure Limit Values

Kieselguhr, soda ash flux-calcined								
Predicted no-effect concentration - PNEC								
Normal value of STP microorganisms				100 mg/l				
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**
Oral			VND	18.7 mg/kg/d				
Inhalation			VND	0.05 mg/m3			VND	0.05 mg/m3

Cristobalite								
Threshold limit value								
Type	**Country**	**TWA/8h Mg/m3**	**Ppm**	**STEL/15min Mg/m3**	**Ppm**			
VLEP	BEL	0.05						
TLV	CZE	0.1						
MAK	DEU	0.15						
VLA	ESP	0.05						
TLV	EST	0.05						
VLEP	FRA	0.05				RESP.		
WEL	GRB	0.3						
OEL	IRL	0.1						
RD	LTU	0.05						
RV	LVA	0.05						
OEL	NLD	0.075				RESP.		
TLV	NOR	0.05				RESP.		
NDS	POL	2				INHAL.		
NDS	POL	0.3				RESP.		
MAK	SWE	0.05				RESP.		
TLV-ACGIH		0.025						

Dipotassium hexfluorotitanate								
Predicted no-effect concentration - PNEC								
Normal value in fresh water	0.131 mg/l							
Normal value in marine water	0.131 mg/l							
Normal value for marine water sediment	4.89 mg/kg/d							
Normal value for water, intermittent release	0.108 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**
Oral					VND	5.2 mg/m3	5.2 mg/kg	5.2 mg/m3
Inhalation					VND	75 mg/kgbw/d	VND	75 mg/kgbw/d

VND - hazard identified but no DNEL/PNEC available. NEA - no exposure expected. NPI - no hazard identified.

Dipotassium hexafluorotitanate:

VLA-ED (daily exposure value): 2.5 mg / (F) / m3 INSHT Guide (data available in the supplier SDS)

Biological indicators: Fluoride in urine. Close of business on 8 mg / L. Before the workshift: 4 mg / g creatinine, after the workshift 7 mg / g creatinine (data available in the supplier SDS).

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.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

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. Personal protective equipment must be CE marked, showing that it complies with applicable standards.

	Provide an emergency shower with face and eye wash station. Exposure levels must be kept as low as possible to avoid significant build-up in the organism. Manage personal protective equipment so as to guarantee maximum protection (e.g. reduction in replacement times).

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	Approved safety goggles (see standard EN 166).
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 (see standard EN 149) or equivalent device, whose class (1, 2 or 3) and effective need, must be defined according to the outcome of risk assessment.

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	No data available
Colour	Green	Vapour density	No data available
Odour	Spearmint	Relative density	1.800 Kg/L
Odour threshold	Not available	Fat solubility	No data available
pH	8 at 20°C (suspension of 10 g of powder per lt of water after 2 min)	Partition coefficient	No data available
Melting point	No data available	Autoignition temperature	No data available
Freezing point	No data available	Viscosity	No data available
Initial boiling point	Not applicable.	Explosive properties	No data available
Flash point	Not applicable.	Oxidising properties	No data available
Evaporation rate	No data available	Solubility	In water: it reacts to form a hydrophilic gel.
Flammability (solid, gas)	No data available		

9.2. Other information

Conductivity	No data available
Surface tension	No data available
Gas group	No data available
Benzene content	No data available
Lead content	No data available
VOC (Volatile organic compounds)	No data available

10. STABILITY AND REACTIVITY

10.1 Reactivity

Dipotassium Hexafluorotitanate	With mineral acids it generates HF.

10.2 Chemical stability

	Stable under normal conditions of use and storage

10.3 Possibility of hazardous reactions

	No hazardous reactions are foreseeable in normal conditions of use and storage

10.4 Conditions to avoid

	None in particular. However the usual precautions used for chemical products should be respected

10.5 Incompatible materials

Dipotassium Hexafluorotitanate	Strong acids

10.6 Hazardous decomposition products

	Information not available

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity	No data available.
Skin corrosion/irritation	No data available.
Serious eye damage/irritation	It may cause eye irritation, see the composition indicated in section 3.2.
Respiratory of skin sensitisation	No data available.
Germ cell mutagenicity	No data available.
Carcinogenicity	No data available.
Reproductive toxicity	No data available.
STOT-single exposure	No data available.
STOT-repeated exposure	May cause damage to lungs through prolonged or repeated exposure through inhalation, see the composition indicated n section 3.2
Aspiration hazard	No data available.

11.1.4 Toxicological Information

Kieselguhr, soda ash flux-calcined	**ORAL Rat LD50:** >2000 mg/kg bw (OECD 401)	**INHAL. Rat LC50:** >2.6 mg/l/1h (OECD 403)
STOT-REPEATED EXPOSURE: the substance is classified in this hazard class because it contains respirable crystalline silica (cristobalite, CAS 14464-46-1), classified as STOT RE 1, as impurity contained in quantity from 1 to 10 %.		

Dipotassium Hexafluorotitanate	**ORAL Rat LD50:** 0.324 mg/kg (OECD 401)	
SERIOUS EYE DAMAGE/IRRITATION: Causes irreversible effect on eyes, (Rabbit, OECD 405)		

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Kieselguhr, soda ash flux-calcined	LC50-for Fish	exceeds the maximum level of solubility of the substance, Oncorhynchus mykiss, OECD 203
	EC50 - for Crustacea.	exceeds the maximum level of solubility of the substance, Daphnia magna, OECD 202
	EC50 - for Algae / Aquatic Plants	exceeds the maximum level of solubility of the substance, Desmodesmus subspicatus, OECD 201
Dipotassium hexfluorotitanate	LC50-for Fish	172,4 mg/l/96h Dario rerio (OECD TG 203)
	EC50 - for Crustacea.	48,2 mg/l/48h Daphnia magna (OECD TG 202)
	EC50 - for Algae / Aquatic Plants	10,82 mg/l/72h Pseudokirchnerella subcapitata (OECD TG 201)

12.2 Persistence and degradability

Kieselguhr, soda ash flux-calcined	The product contains exclusively inorganic compounds non-biodegradable (data available in the SDS of the supplier).
Dipotassium hexfluorotitanate	

12.3 Bio accumulative potential

Kieselguhr, soda ash flux-calcined	The product does not contain any substances expected to be bioaccumulating (data available in the SDS of the supplier).
Dipotassium hexfluorotitanate	The product has a potential to bioaccumulate in aquatic organisms (data available in the SDS of the supplier).

12.4 Mobility in soil

Kieselguhr, soda ash flux-calcined	Mobility: not relevant due to the physical state of the product. The product is insoluble in water.

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%.

12.6 Other adverse effects

	No data is available on this product.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

	Dispose of in compliance with all local and national regulations.

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.

Disposal Methods

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

Disposal of packaging

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

14. TRANSPORT INFORMATION

14.1 UN number

	Not applicable.

14.2 UN proper shipping name

	Not applicable.

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.

14.5 Environmental hazards

Environmental hazards Marine pollutant	Not applicable.

14.6 Special precautions for user

	Not applicable.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code.

	Information not relevant.

15. REGULATORY INFORMATION

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

Regulations	COMMISION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation,

	Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

15.2 Chemical Safety Assessment

	No data available.

16. OTHER INFORMATION

Other information

Text of Hazard Statements in Section 2 and 3	Acute Tox.4: H302: Harmful if swallowed. Eye Dam. 1: H318 – Causes serious eye damage. Eye Irrit. 2: H319 – Causes serious eye irritation. STOT Re 2: H373 – may cause damage to organs through prolonged or repeated exposure.

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.