

Safety data sheet

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

1.1. Product identifier

Product name Italgin – Chromatic Alginate

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

Intended use Chromatic alginate without dust for dental use.
Uses advised against No use advised against.

1.3. Details of the supplier of the safety data sheet

Name BMS DENTAL S.R.L.
Full address VIA M.BUONARROTI, 21/23/25
District and Country CAPANNOLI (Pi) - ITALY

e-mail address of the competent person info@bmsdental.it
responsible for the Safety Data Sheet Dr. Abdallah Badawneh

1.4. Emergency telephone number

For urgent inquiries refer to

CAV Italia: Centro Antiveleni di Milano: 02 66101029; Centro Antiveleni di Firenze: 055

7947819; Centro Antiveleni di Roma: 06 3054343; Centro Antiveleni di Roma: 06
49978000; Centro Antiveleni di Napoli: 081 7472870

Austria Poison Control Centre Emergency helpline: +43 1 406 43 43

Belgium Centre Antipoisons: 070 245 245

Bulgaria National Toxicology Center, Hospital for Active Medical Treatment and Emergency Medicine "N.I.Pirogov": +359 2 9154 409

Czech Republic Toxikologické informační středisko: Telefon: +420 224 919 293, +420 224 915 402

Hungary National Emergency Phone Number: +36 80 20 11 99

Lithuania National Emergency Telephone Number (Neatidėliotina informacija apsinuodijus): +370 5 236 20 52 or +370 687 53378

Portugal Centro di informazioni Antiveleni: 808 250 143

Romania Biroul pentru Regulamentul Sanitar International si Informare Toxicologica

Tel. 021.318.36.06 (direct)

Poland KRAJOWE CENTRUM INFORMACJI TOKSYKOLOGICZNEJ tel.: 42 631 47 24 , 42 631 47 25

España:Servicio de Información Toxicológica (SIT) + 34 91 562 04 20 (24h/365 días)

France:Numéro ORFILA (INRS-France): + 33 (0)1 45 42 59 59 (24h/ 7 jours sur 7)

UK Emergency number: 844 892 0111 (24 hours)

Deutschland, Berlin Tel.: 030/19240 (Notruf), Fax: 030/30 686 799

USA Emergency Phone Number (24 hours) CHEMTREC (800-424-9300)

SECTION 2. Hazards identification.

2.1. Classification of the substance or mixture.

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 EC Regulation 1907/2006 and subsequent amendments. Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Specific target organ toxicity - repeated exposure, category 2 H373

May cause damage to organs through prolonged or repeated exposure.

2.2. Label elements.

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.



Signal words: Warning

Hazard statements:

H373 May cause damage to lungs through prolonged or repeated exposure via inhalation.

Precautionary statements:

P260 Do not breathe dust.

P270 Do not eat, drink or smoke when using this product.

P314 Get medical advice / attention if you feel unwell.

Contains: Kieselguhr, soda ash flux-calcined

2.3. Other hazards.

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

SECTION 3. Composition/information on ingredients.

3.1. Substances.

Information not relevant.

3.2. Mixtures.

Contains:

Identification.	Conc. %.	Classification 1272/2008 (CLP).
Kieselguhr, soda ash flux-calcined CAS. 68855-54-9 EC. 272-489-0 INDEX. - Reg. no. 01-2119488518-22	65 - 80	STOT RE 2 H373
dipotassium hexafluorotitanate CAS. 16919-27-0 EC. 240-969-9 INDEX. - Reg. no. 01-2119978268-20	1 - 3	Acute Tox. 3 H331, Acute Tox. 4 H302, Eye Irrit. 2 H319, Skin Irrit. 2 H315, STOT SE 3 H335

Note: Upper limit is not included into the range.

The full wording of hazard (H) phrases is given in section 16 of the sheet.

SECTION 4. First aid measures.

4.1. Description of first aid measures.

EYES: 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: Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention immediately. Wash contaminated clothing before using it again.
INHALATION: Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention immediately.
INGESTION: Get medical advice/attention immediately. Do not induce vomiting. Do not administer anything not explicitly authorised by a doctor.
PROTECTIVE MEASURES FOR THE FIRST RESCUE WORKERS: for PPE (personal protection equipment) required for first aid refer to section 8.2 of this safety data sheet.

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

For symptoms and effects caused by the contained substances, see chap. 11.

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

Information not available.

SECTION 5. Firefighting measures.

5.1. Extinguishing media.

SUITABLE EXTINGUISHING EQUIPMENT

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

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

5.2. Special hazards arising from the substance or mixture.

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products. The product is combustible and, when the powder is released into the air in sufficient concentrations and in the presence of a source of ignition, it can create explosive mixtures with air. Fires may start or get worse by leakage of the solid product from the container, when it reaches high temperatures or through contact with sources of ignition.

5.3. Advice for firefighters.

GENERAL INFORMATION

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 into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

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).

SECTION 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 the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions.

The product must not penetrate into the sewer system or come into 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 recovery or disposal. If there are no contraindications, use jets of water to eliminate product residues. Make sure the leakage site is well aired. Check incompatibility for container material in section 7. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections.

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 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.

Storage class TRGS 510 (Germany): 11

7.3. Specific end use(s).

Information not available.

SECTION 8. Exposure controls/personal protection.

8.1. Control parameters.

BEL	Belgique	AR du 11/3/2002. La liste est mise à jour pour 2010
CZE	Česká Republika	Nařízení vlády č. 361/2007 Sb. kterým se stanoví podmínky ochrany zdraví při práci
DEU	Deutschland	MAK-und BAT-Werte-Liste 2012
ESP	España	INSHT - Límites de exposición profesional para agentes químicos en España 2015
EST	Eesti	Töökeskonna keemiliste ohutegurite piirnormid 1. Vastu võetud 18.09.2001 nr 293 RT I 2001, 77, 460 - Redaktsiooni jõustumise kp: 01.01.2008
FRA	France	JORF n°0109 du 10 mai 2012 page 8773 texte n° 102
GRB	United Kingdom	EH40/2005 Workplace exposure limits
IRL	Éire	Code of Practice Chemical Agent Regulations 2011
LTU	Lietuva	DĖL LIETUVOS HIGIENOS NORMOS HN 23:2007 CHEMINIŲ MEDŽIAGŲ 2007 m. spalio 15 d. Nr. V-827/A1-287
LVA	Latvija	Ķīmisko vielu aroda ekspozīcijas robežvērtības (AER) darba vides gaisā 2012
NLD	Nederland	Databank of the social and Economic Concil of Netherlands (SER) Values, AF 2011:18
NOR	Norge	Veiledning om Administrative normer for forurensning i arbeidsatmosfære
POL	Polska	ROZPORZĄDZENIE MINISTRA PRACY I POLITYKI SPOŁECZNEJ z dnia 16 grudnia 2011r
SWE	Sverige	Occupational Exposure Limit Values, AF 2011:18
	TLV-ACGIH	ACGIH 2014

Kieselguhr, soda ash flux-calcined

Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers.			Effects on workers				
	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral.			VND	18,7 mg/kg/d				
Inhalation.			VND	0,05 mg/m ³			VND	0,05 mg/m ³

CRISTOBALITE

Threshold Limit Value.

Type	Country	TWA/8h		STEL/15min	
		mg/m ³	ppm	mg/m ³	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			

Legend:

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

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. Si raccomanda di considerare nel processo di valutazione del rischio i valori limite di esposizione professionale previsti dall' ACGIH per le polveri inerti non altrimenti classificate (PNOC frazione respirabile: 3 mg/mc; PNOC frazione inalabile: 10 mg/mc). In caso di superamento di tali limiti si consiglia l'utilizzo di un filtro di tipo P la cui classe (1, 2 o 3) dovrà essere scelta in base all'esito della valutazione del rischio.

8.2. Exposure 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.

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).

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.

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 PROTECTION

Wear airtight protective goggles (see standard EN 166).

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.

ENVIRONMENTAL EXPOSURE CONTROLS.

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

SECTION 9. Physical and chemical properties.

9.1. Information on basic physical and chemical properties.

Appearance	powder
Colour	white
Odour	characteristic
Odour threshold.	Not available.
pH.	8 at 20°C (suspension of 10 g of powder per liter of water after 2 min)
Melting point / freezing point.	Not available.
Initial boiling point.	Not applicable.
Boiling range.	Not available.
Flash point.	Not applicable.
Evaporation Rate	Not available.
Flammability of solids and gases	Not available.
Lower inflammability limit.	Not available.
Upper inflammability limit.	Not available.
Lower explosive limit.	Not available.
Upper explosive limit.	Not available.
Vapour pressure.	Not available.
Vapour density	Not available.
Relative density.	1,800 Kg/l
Solubility	In water: it reacts to form a hydrophilic gel.
Partition coefficient: n-octanol/water	Not available.
Auto-ignition temperature.	Not available.
Decomposition temperature.	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidising properties	Not available.

9.2. Other information.

Information not available.

SECTION 10. Stability and reactivity.

10.1. Reactivity.

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

DIPOTASSIUM HEXAFLUOROTITANATE

With mineral acids it generates HF.

10.2. Chemical stability.

The product is stable in 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.

SECTION 11. Toxicological information.

11.1. Information on toxicological effects.

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.

Data available for the mixture:

ACUTE TOXICITY: no data available.

SKIN CORROSION/IRRITATION: no data available.

SERIOUS EYE DAMAGE/IRRITATION: no data available.

RESPIRATORY OR 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 in Section 3.2.

ASPIRATION HAZARD: no data available.

Data available for the substances in the mixture:

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 %.

DIPOTASSIUM HEXAFLUOROTITANATE

ACUTE TOXICITY

LD50 (Oral).324 mg/kg Rat (Data available in the supplier safety data sheet).

ACUTE TOXICITY INHALATION: toxic if inhaled, classification available in the supplier SDS.

SKIN CORROSION/IRRITATION: causes skin irritation, classification available in the supplier SDS.

SERIOUS EYE DAMAGE/IRRITATION: causes serious eye irritation, classification available in the supplier SDS.

STOT-SINGLE EXPOSURE: may cause respiratory irritation, classification available in the supplier SDS.

SECTION 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 HEXAFLUOROTITANATE

LC50 - for Fish.

172,4 mg/l/96h Danio 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.

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

12.2. Persistence and degradability.

DIPOTASSIUM HEXAFLUOROTITANATE

Biodegradability: Information not available.

KIESELGUHR, SODA ASH FLUX-CALCINED

The product contains exclusively inorganic compounds non-biodegradable (data available in the SDS of the supplier).

12.3. Bioaccumulative 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 HEXAFLUOROTITANATE

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.

Information not available.

SECTION 13. Disposal considerations.

13.1. Waste treatment methods.

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.

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

CONTAMINATED PACKAGING

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

SECTION 14. Transport information.

14.1. UN number.

Not applicable.

14.2. UN proper shipping name.

Not applicable.

14.3. Transport hazard class(es).

Not applicable.

14.4. Packing group.

Not applicable.

14.5. Environmental hazards.

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.

SECTION 15. Regulatory information.

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

Seveso category. None.

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

None.

Substances in Candidate List (Art. 59 REACH).

None.

Substances subject to authorisation (Annex XIV REACH).

None.

Substances subject to exportation reporting pursuant to (EC) Reg. 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.

German regulation on the classification of substances hazardous to water (VwVwS 2005).

WGK 1: Low hazard to waters

15.2. Chemical safety assessment.

No chemical safety assessment has been processed for the mixture and the substances it contains.

SECTION 16. Other information.

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

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 Irrit. 2	Eye irritation, category 2
Skin Irrit. 2	Skin irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
H331	Toxic if inhaled.
H302	Harmful if swallowed.
H373	May cause damage to organs through prolonged or repeated exposure.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 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 NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 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 STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EU) 1907/2006 (REACH) of the European Parliament
 2. Regulation (EU) 1272/2008 (CLP) of the European Parliament
 3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
 4. Regulation (EU) 2015/830 of the European Parliament
 5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
 6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
 7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
 9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
- The Merck Index. - 10th Edition
 - Handling Chemical Safety
 - INRS - Fiche Toxicologique (toxicological sheet)
 - Patty - Industrial Hygiene and Toxicology
 - N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

- ECHA website

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

Changes to previous review:

The following sections were modified:

01 / 02 / 03 /. 04 / 05 / 06 /. 07 / 08 / 09./ 10 / 11 / 12 /. 13 / 14 / 15 / 16.