SAFETY DATA SHEET

Prepared by: N Jenkins
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Section 1 – Product and Company Identification

1.1 Product Name: ISOLUTE HM – N

1.2 Product Code: 9800

1.3 Recommended Use: Laboratory chemical

Uses advised against: Not for therapeutic or diagnostic use

1.4 Company Name:
Biotage GB Limited,
Dyffryn Business Park,
Hengoed, CF82 7TS
UK

1.5 Contact details:

Europe
Telephone: +46 18 56 59 11
8:00a.m. – 5:00p.m. CET
e-mail: eu-1-pointsupport@biotage.com

North America
Telephone: +1 800 446 4752
8:00a.m. – 5:00p.m. EST
Press (3) at the auto attendant
e-mail: us-1-pointsupport@biotage.com

Japan
Telephone: +81 3 5627 3123
9:00a.m. – 6:00p.m. local time
e-mail: jp-1-pointsupport@biotage.com

China
Telephone: +86 21 2898 6655
8:30a.m. – 5:30p.m. local time
e-mail: cn–1–pointsupport@biotage.com

Section 2 – Hazards Identification

2.1 Classification of the product

Classification according to Regulation (EC) No 1272 / 2008 [EU – GHS / CLP]

Eye irritation (Category 2)

Specific target organ toxicity – single exposure (Category 3)

Specific target organ toxicity – repeated exposure, inhalation (Category 2)

Classification according to EU Directives 67 / 548 / EEC or 1999 / 45 / EC

Harmful: danger of serious damage to health by prolonged exposure through inhalation. Irritating to eyes and respiratory system

2.2 Label elements

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

Pictogram

Signal word: Warning

Hazard Statements

H319	Causes serious eye irritation
H335	May cause respiratory irritation
H373	May cause damage to organs through prolonged or repeated exposure if inhaled

Precautionary statements

P261	Avoid breathing dust / fume / gas / mist / vapours / spray
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do so. Continue rinsing

Supplemental Hazard Statements

None

According to European Directive 67 / 548 / EEC as amended

Hazard symbol

R – phrases

R36 / 37	Irritating to eyes and respiratory system
R 48 / 20	Harmful: danger of serious damage to health by prolonged exposure through inhalation

S – phrases

S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

2.3 Other hazards

None

Section 3 – Composition/Information on Ingredients

Name:	**ISOLUTE HM – N**
Synonyms:	Filter agent; Celite

Component	**CAS – No.**	**EC – No.**	**Classification**	**Concentration**
Diatomaceous earth (calcined)	68855 – 54 – 9	272 – 489 – 0	Eye Irrit. 2; STOT SE 3; STOT RE 2; H319, H335, H373 Xn, R36 / 37 – R48 / 20	-
Silicon dioxide	14464 – 46 – 1	238 – 455 – 4	STOT RE 2; H373 Xn, R48 / 20	50 – 100 %
Quartz	14808 – 60 – 7	238 – 878 – 4	STOT RE 2; H373 Xn, R48 / 20	≤ 4%

For the full text of the Hazard statements and R – phrases mentioned in this section, see section 16

Section 4 – First Aid Measures

4.1 Inhalation: If inhaled, move affected person to fresh air. If breathing is difficult give oxygen. If breathing has stopped give artificial respiration. Seek medical attention

4.2 Skin Contact: Wash with soap and plenty of water. Seek medical attention

4.3 Eye Contact: Wash thoroughly with plenty of water for at least 15 minutes, separating the eyelids with the fingers. Seek medical attention

4.4 Ingestion: Wash out mouth with water if person is conscious. Never give anything by mouth to an unconscious person. Seek medical attention

4.5 Most important symptoms and effects, both acute and delayed This product contains crystalline silica (CS), which is considered a hazard by inhalation. IARC has classified inhalation of CS as a carcinogen for humans (Group 1). CS is listed by NTP as a known human carcinogen. Inhalation of CS is also a known cause of silicosis, a noncancerous lung disease. Prolonged inhalation of crystalline silica may result in silicosis, a disabling pulmonary fibrosis characterised by fibrotic changes and military nodules in the lungs, a dry cough, shortness of breath, emphysema, decreased chest expansion, and increased susceptibility to tuberculosis. In advanced stages, loss of appetite, pleuritic pain, and total incapacity to work. Advanced silicosis may result in death due to cardiac failure or destruction of lung tissue. The chronic health risks are associated with respirable particles of 3 – 4 μm over protracted periods of time. Currently, there is limited understanding of the mechanisms of quartz toxicity, including its mechanisms for lung carcinogenicity. Additional studies are needed to determine whether the cell transforming activity of quartz is related to its carcinogenic potential. Respirable silica may cause immune system disorders, increased risk to develop pulmonary tuberculosis, and increased incidence of kidney disease

Section 5 – Fire-Fighting Measures

5.1 Suitable Extinguishing Media

Use dry chemical, CO2, water spray or alcohol foam extinguishers appropriate to surrounding conditions

5.2 Unusual Fire Hazards and Explosion Hazards

This material is not flammable

5.3 Special protective equipment for Fire Fighters

Wear self contained breathing apparatus for fire fighting if necessary

Section 6 – Accidental Release Measures

6.1 Personal precautions

Ventilate the area thoroughly and shut off sources of ignition. Use protective equipment as described in Section 8. Avoid raising dust. Avoid breathing dust. Evacuate personnel to safe areas

6.2 Environmental Precautions

Do not let product enter drains

6.3 Methods and materials for containment and cleaning up

Pick up without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

Section 7 – Handling and Storage

7.1 Precautions for safe handling

Provide appropriate exhaust ventilation at places where dust is formed. Avoid contact with skin and eyes

7.2 Conditions for safe storage

Keep container tightly closed in a dry and well – ventilated place. Store in a cool place, out of direct sunlight and away from incompatible substances

Section 8 – Exposure Controls / Personal Protection

Components with workplace control parameters

Components	CAS No.	Value	Control Parameters	Basis
Diatomaceous earth (calcined)	68855 – 54 – 9	TWA	6 mg / m^3	UK. EH40 WEL – Workplace Exposure Limits
		TWA	2.4 mg / m^3	UK. EH40 WEL – Workplace Exposure Limits
Silicon dioxide	14464 – 46 – 1	TWA	0.1 mg / m^3	UK. EH40 WEL – Workplace Exposure Limits
		TWA	0.1 mg / m^3	UK. EH40 WEL – Workplace Exposure Limits
Quartz	14808 – 60 – 7	TWA	0.1 mg / m^3	UK. EH40 WEL – Workplace Exposure Limits
		TWA	0.1 mg / m^3	UK. EH40 WEL – Workplace Exposure Limits
Remarks	For the purposes of these limits, respirable dust and inhalable dust are those fractions of the airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/3 General methods for sampling and gravimetric analysis of respirable and inhalable dust, as amended by the ISO / CEN convention. The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10mg/m^3 8 – hour TWA of inhalable dust or 4mg/m^3 8 – hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed above these levels. Advice on control is given in EH44 and in the great majority of workplaces reasonable control measures will normally keep exposures below these levels. However some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limit. Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit – setting purposes termed 'inhalable' and 'respirable'. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/3. Where dusts contain components that have their own assigned workplace exposure limit, all relevant limits should be complied with. Where no specific short – term exposure is listed, a figure three times the long – term exposure should be used.			

8.1 Personal protective equipment

Respiratory protection

For nuisance exposures use type N95 (US) or type P1 (EU EN 143) dust masks. For higher level protection use type OV / AG / P99 (US) or type ABEK – P2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU)

Hand protection

Handle with gloves. The selected protective gloves have to satisfy the specifications of EU Directive 89 / 686 / EEC and the standard EN 374 derived from it. Gloves must be inspected prior to use. Use proper glove removal technique (without touching the outer surface of the glove) to avoid skin contact with product. Dispose of gloves after use in accordance with applicable regulations and good laboratory practice. Wash and dry hands

Eye protection

Safety glasses with side – shields conforming to EN 166. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU)

Skin and body protection

Choose body protection in relation to its type, the concentration and the amount of dangerous substances, and to the specific workplace

Hygiene measures

Handle in accordance with good laboratory hygiene and safe practice. Wash hands before breaks and at the end of the workday

Section 9 – Physical and Chemical Properties

9.1 Appearance

Form	Granular powder
Colour	White / off – white, with occasional black specks

9.2 Safety data

pH	No data available
Melting point	No data available
Boiling point	No data available
Flash point	No data available
Ignition temperature	No data available
Lower explosion limit	No data available
Upper explosion limit	No data available
Water solubility	No data available

Section 10 – Stability and Reactivity

10.1 Chemical stability
No data available

10.2 Conditions to avoid
No data available

10.3 Materials to avoid
Strong acids, hydrogen fluoride

10.4 Hazardous decomposition products
Hazardous decomposition products formed under fire conditions – no data available

Section 11 – Toxicological Information

To the best of our knowledge, the toxicological properties of this material have not been fully investigated

(a) Acute toxicity
No data available

(b) Skin corrosion / irritation
No data available

(c) Serious eye damage / eye irritation
No data available

(d) Respiratory or skin sensitisation
No data available

(e) Germ cell mutagenicity
No data available

(f) Carcinogenicity

IARC	1 – Group 1: Carcinogenic to humans (silicon dioxide)
IARC	1 – Group 1: Carcinogenic to humans (quartz)
IARC	A4 – Not classifiable as a human carcinogen (diatomaceous earth (calcined))
	3 – Group 3: Not classifiable as to its carcinogenicity to humans (diatomaceous earth (calcined))

(g) Reproductive toxicity
No data available

(h) Specific target organ toxicity – single exposure
No data available

(i) Specific target organ toxicity – repeated exposure
No data available

(j) Aspiration hazard
No data available

(k) Potential health effects

Inhalation	Harmful if inhaled. Causes respiratory tract irritation
Ingestion	Harmful if swallowed
Skin	May cause skin irritation
Eyes	Causes serious eye irritation

Section 12 – Ecological Information

The eco- toxicological properties of this material have not been fully investigated

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bio – accumulative potential

Does not bioaccumulate

12.4 Mobility in soil

No data available

12.5 PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

Section 13 – Disposal Considerations

13.1 Product

Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber

13.2 Contaminated packaging

Dispose of as unused product

Section 14 – Transport Information

Not classified as dangerous goods by ADR / RID, IMDG, or IATA

Section 15 – Regulatory Information

This safety data sheet complies with the requirements of Regulation (EC) No. 1907 / 2006.
Caution: This substance has not been fully tested (EC)

Country Specific

Germany: WGK: 3 (Self – classification)

US (TSCA) Manufactured for research and development only. Note: Chemical substances that are manufactured or imported in small quantities solely for use in research and development are not subject to the notification requirements of the Toxic Substance Control Act (TSCA), 15 USC 2604 (h) et seq. Reference – 40 CFR 720.36

Section 16 – Other Information

Text of Hazard codes and R – phrases mentioned in section 3

Eye Irrit.	Eye irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H373	May cause damage to organs trough prolonged or repeated exposure if inhaled
STOT RE	Specific target organ toxicity – repeated exposure
STOT SE	Specific target organ toxicity – single exposure
X_n	Harmful
R36 / 37	Irritating to eyes and respiratory system
R 48 / 20	Harmful: danger of serious damage to health by prolonged exposure through inhalation

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Key to Abbreviations

CAS: Chemical Abstract Service. **NIOSH**: National Institute for Occupational Safety & Health. **IARC**: International Agency for Research on Cancer. **NTP**: National Toxicology Program. **ADR / RID**: Agreement on Dangerous Goods by Road / Regulations Concerning the transport of Dangerous Goods by Rail. **IMDG**: International Maritime Dangerous Goods Code. **IATA**: International Air Transport Association.