

SAFETY DATA SHEET

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

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

1.1. Product identifier

Product name **KRYO SPRAY**
Chemical name and synonym **UFI: 3PK6-K02M-K00S-NRWV**

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

Intended use **Rapid freezing spray for histology**

1.3. Details of the supplier of the safety data sheet

Name **KALTEK srl**
Full address **Via Liguria, 29**
District and Country **35020 SAONARA (PD)**
ITALIA
Tel. **+39 049 8703410 (orario: 8,45-13,00/14,30-18,15)**
Fax **+39 049 8703383**

e-mail address of the competent person responsible for the Safety Data Sheet

qualit@kaltek.it

1.4. Emergency telephone number

For urgent inquiries refer to **Please contact the nearest Tossicology and Poison Center**

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 (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.

Hazard classification and indication:

Aerosol, category 1	H222	Extremely flammable aerosol.
	H229	Pressurised container: may burst if heated.

2.2. Label elements

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

Hazard pictograms:



Signal words: **Danger**

Hazard statements:

H222	Extremely flammable aerosol.
H229	Pressurised container: may burst if heated.

Precautionary statements:

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P251	Do not pierce or burn, even after use.
P410+P412	Protect from sunlight. Do not expose to temperatures exceeding 50°C / 122°F.
P211	Do not spray on an open flame or other ignition source.

2.3. Other hazards

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

The product does not contain substances with endocrine disrupting properties in concentration $\geq$ 0.1%.

SECTION 3. Composition/information on ingredients

3.1. Substances

Information not relevant

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification (EC) 1272/2008 (CLP)
BUTANE		
INDEX 601-004-00-0	$50 \leq x < 100$	Flam. Gas 1A H220, Press. Gas (Liq.) H280, Classification note according to Annex VI to the CLP Regulation: C, U

EC 203-448-7

CAS 106-97-8



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PROPANE

INDEX 601-003-00-5

 $9 \leq x < 30$

Flam. Gas 1A H220, Press. Gas (Liq.) H280, Classification note according to Annex VI to the CLP Regulation: U

EC 200-827-9

CAS 74-98-6

REACH Reg. 01-2119486944-21

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

The product is an aerosol containing propellants. For the purposes of calculation of the health hazards, propellants are not considered (unless they have health hazards). The percentages indicated are inclusive of the propellants.

Percentage of propellants: 100,00 %

SECTION 4. First aid measures**4.1. Description of first aid measures**

No episodes of harm to the staff authorised to use the product have been reported. The following general measures should be adopted as necessary:

INHALATION: Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention.

INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Do not give anything by mouth to an unconscious person.

EYES and SKIN: Wash with plenty of water. In the event of persistent irritation, get medical advice/attention.

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

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

If overheated, aerosol cans can deform, explode and be propelled considerable distances. Put a protective helmet on before approaching the fire. Do not breathe combustion products.

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.

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**

Eliminate all sources of ignition (cigarettes, flames, sparks, etc.) from the leakage site. Send away individuals who are not suitably equipped. Wear protective gloves / protective clothing / eye protection / face protection.

6.2. Environmental precautions

Do not disperse in the environment.

6.3. Methods and material for containment and cleaning up

Use inert absorbent material to soak up leaked product. Make sure the leakage site is well aired. 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**

Avoid bunching of electrostatic charges. Do not spray on flames or incandescent bodies. Vapours may catch fire and an explosion may occur; vapour accumulation is therefore to be avoided by leaving windows and doors open and ensuring good cross ventilation. Do not eat, drink or smoke during use. Do not breathe spray.

7.2. Conditions for safe storage, including any incompatibilities

Store in a place where adequate ventilation is ensured, away from direct sunlight at a temperature below 50°C / 122°F, away from any combustion sources.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection**8.1. Control parameters**

Regulatory References:

BGR	България	НАРЕДБА № 13 ОТ 30 ДЕКЕМВРИ 2003 Г. ЗА ЗАЩИТА НА РАБОТЕЩИТЕ ОТ РИСКОВЕ, СВЪРЗАНИ С ЕКСПОЗИЦИЯ НА ХИМИЧНИ АГЕНТИ ПРИ РАБОТА (изм. ДВ. бр.5 от 17 Януари 2020г.)
CHE	Suisse / Schweiz	Valeurs limites d'exposition aux postes de travail: VME/VLE (SUVA). Grenzwerte am Arbeitsplatz: MAK

ESP	España	(SUVA)
EST	Eesti	Límites de exposición profesional para agentes químicos en España 2021
FRA	France	Ohtlike kemikaalide ja neid sisaldavate materjalide kasutamise töötavishoiu ja tööohutuse nõuded ning töökesskonna keemiliste ohtegurite piirnordid [RT I, 17.10.2019, 1 - jõust. 17.01.2020]
GRC	Ελλάδα	Valeurs limites d'exposition professionnelle aux agents chimiques en France. ED 984 - INRS
HRV	Hrvatska	Π.Δ. 26/2020 (ΦΕΚ 50/Α` 6.3.2020) Εναρμόνιση της ελληνικής νομοθεσίας προς τις διατάξεις των οδηγιών 2017/2398/ΕΕ, 2019/130/ΕΕ και 2019/983/ΕΕ «για την τροποποίηση της οδηγίας 2004/37/ΕΚ ``σχετικά με την προστασία των εργαζομένων από τους κινδύνους που συνδέονται με την έκθεση σε καρκινογόνους ή μεταλλαξιγόνους παράγοντες κατά την εργασία``»
LVA	Latvija	Pravilnik o izmjenama i dopunama Pravilnika o zaštiti radnika od izloženosti opasnim kemikalijama na radu, graničnim vrijednostima izloženosti i biološkim graničnim vrijednostima (NN 1/2021)
ROU	România	Grozījumi Ministru kabineta 2007. gada 15. maija noteikumos Nr. 325 "Darba aizsardzības prasības saskarē ar ķīmiskajām vielām darba vietās" (prot. Nr. 32 18. §; prot. Nr. 1 22. §)
SVN	Slovenija	Hotărârea nr. 53/2021 pentru modificarea hotărârii guvernului nr. 1.218/2006, precum și pentru modificarea și completarea hotărârii guvernului nr. 1.093/2006
GBR	United Kingdom	Pravilnik o varovanju delavcev pred tveganji zaradi izpostavljenosti kemičnim snovem pri delu (Uradni list RS, št. 100/01, 39/05, 53/07, 102/10, 43/11 – ZVZD-1, 38/15, 78/18 in 78/19)
	TLV-ACGIH	EH40/2005 Workplace exposure limits (Fourth Edition 2020)
		ACGIH 2021

BUTANE					
Threshold Limit Value					
Type	Country	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
TLV	BGR	1900			
MAK	CHE	1900	800	7600	3200
VME/VLE	CHE	1900	800	7600	3200
VLA	ESP		1000		
TLV	EST	1500	800		
VLEP	FRA	1900	800		
TLV	GRC	2350	1000		
GVI/KGVI	HRV	1450	600	1810	750
RV	LVA	300			
MV	SVN	2400	1000	9600	4000
WEL	GBR	1450	600	1810	750
WEL	GBR		4		
TLV-ACGIH					1000

PROPANE					
Threshold Limit Value					
Type	Country	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
TLV	BGR	1800			
MAK	CHE	1800	1000	7200	4000
VME/VLE	CHE	1800	1000	7200	4000
VLA	ESP		1000		
TLV	EST	1800	1000		
TLV	GRC	1800	1000		
RV	LVA	1800	100		
TLV	ROU	1400	778	1800	1000
MV	SVN	1800	1000	7200	4000

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

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.

HAND PROTECTION

None required.

SKIN PROTECTION

Wear category I professional long-sleeved overalls and safety footwear (see Regulation 2016/425 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

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, a mask with a type AX filter combined with a type P filter should be worn (see standard EN 14387).

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

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**

Properties	Value	Information
Appearance	aerosol	
Colour	colourless	
Odour	odourless	
Melting point / freezing point	not available	
Initial boiling point	not applicable	
Flammability	not available	
Lower explosive limit	1,8 % (v/v)	
Upper explosive limit	9,5 % (v/v)	
Flash point	-104 °C	
Auto-ignition temperature	not available	
Decomposition temperature	not available	
pH	not available	
Kinematic viscosity	not available	
Solubility	not applicable	
Partition coefficient: n-octanol/water	not available	
Vapour pressure	3446,55 mmHg	
Density and/or relative density	0,52	
Relative vapour density	not available	
Particle characteristics	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

VOC (Directive 2010/75/EU) 100,00 % - 523,74 g/litre

VOC (volatile carbon) 82,35 % - 431,29 g/litre

SECTION 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 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

Avoid overheating.

10.5. Incompatible materials

Strong reducing or oxidising agents, strong acids or alkalis, hot material.

10.6. Hazardous decomposition products

Information not available

SECTION 11. Toxicological information

According to currently available data, this product has not yet produced health damages. Anyway, it must be handled according to good industrial practices.

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

ACUTE TOXICITY

ATE (Inhalation) of the mixture: Not classified (no significant component)

ATE (Oral) of the mixture: Not classified (no significant component)

ATE (Dermal) of the mixture: Not classified (no significant component)

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

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

Does not meet the classification criteria for this hazard class

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.

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

Information not available

12.2. Persistence and degradability

BUTANE

Solubility in water 0,1 - 100 mg/l

Rapidly degradable

PROPANE

Solubility in water 0,1 - 100 mg/l

Rapidly degradable

12.3. Bioaccumulative potential

BUTANE

Partition coefficient: n-octanol/water 1,09

PROPANE

Partition coefficient: n-octanol/water 1,09

12.4. Mobility in soil

Information not available

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 $\geq$ than 0,1%.

12.6. Endocrine disrupting properties

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.

12.7. Other adverse effects

Information not available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

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 must be performed through an authorised waste management firm, in compliance with national and local regulations. Waste transportation may be subject to ADR restrictions.

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 or ID number

ADR / RID, IMDG, IATA: 1950

14.2. UN proper shipping name

ADR / RID: AEROSOLS

IMDG: AEROSOLS

IATA: AEROSOLS, FLAMMABLE

14.3. Transport hazard class(es)

ADR / RID: Class: 2 Label: 2.1

IMDG: Class: 2 Label: 2.1

IATA: Class: 2 Label: 2.1





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14.4. Packing group

ADR / RID, IMDG, IATA: -

14.5. Environmental hazards

ADR / RID: NO

IMDG: NO

IATA: NO

14.6. Special precautions for user

ADR / RID:	HIN - Kemler: --	Limited Quantities: 1 L	Tunnel restriction code: (D)
	Special provision: -		
IMDG:	EMS: F-D, S-U	Limited Quantities: 1 L	
IATA:	Cargo:	Maximum quantity: 150 Kg	Packaging instructions: 203
	Pass.:	Maximum quantity: 75 Kg	Packaging instructions: 203
	Special provision:	A145, A167, A802	

14.7. Maritime transport in bulk according to IMO instruments

Information not relevant

SECTION 15. Regulatory information

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

Seveso Category - Directive 2012/18/EU: P3a

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

Product

Point 40

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): NoneSubstances subject to exportation reporting pursuant to Regulation (EU) 649/2012: NoneSubstances subject to the Rotterdam Convention: NoneSubstances subject to the Stockholm Convention: None

Healthcare controls

Information not available

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16. Other information

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

Flam. Gas 1A	Flammable gas, category 1A
Aerosol 1	Aerosol, category 1
Aerosol 3	Aerosol, category 3
Press. Gas (Liq.)	Liquefied gas
H220	Extremely flammable gas.
H222	Extremely flammable aerosol.
H229	Pressurised container: may burst if heated.
H280	Contains gas under pressure; may explode if heated.

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 as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- 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 as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
 2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
 3. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
 4. Regulation (EC) 790/2009 (I Atp. CLP) 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
 10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
 11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
 12. Regulation (EU) 2016/1179 (IX Atp. CLP)
 13. Regulation (EU) 2017/776 (X Atp. CLP)
 14. Regulation (EU) 2018/669 (XI Atp. CLP)
 15. Regulation (EU) 2019/521 (XII Atp. CLP)
 16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
 17. Regulation (EU) 2019/1148
 18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
 19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
 20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)
 21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)
 22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)
- 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
 - IFA GESTIS website
 - ECHA website
 - Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

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.

CALCULATION METHODS FOR CLASSIFICATION

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.

Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.

Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

Changes to previous review:

The following sections were modified:

01 / 02 / 03 / 08 / 09 / 11 / 12 / 15 / 16.