



SAFETY DATA SHEET
NOVAPLUS Surgical Instrument Lubricant

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name NOVAPLUS Surgical Instrument Lubricant

Product No. NPL054 – NPL055

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

Identified uses Lubricant for surgical instruments and medical devices

1.3. Details of the supplier of the safety data sheet

Supplier Case Medical Inc.
19 Empire Blvd.
South Hackensack
NJ 07606
USA
Tel: 201-313-1999
Fax: 201-373-9090
Contact Person SDS Contact: DCM Compliance, info@dcmcompliance.com

1.4. Emergency telephone number

201-313-1999

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

Physical and Chemical	Not classified.
Hazards	
Human health	Not classified.
Environment	Not classified.

Classification (1999/45/EEC) Not classified.

The Full Text for all R-Phrases and Hazard Statements are Displayed in Section 16.

2.2. Label elements

Label In Accordance With (EC) No. 1272/2008
No pictogram required.

2.3. Other hazards

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

POTASSIUM HYDROXIDE		< 1%
CAS-No.: 1310-58-3	EC No.: 215-181-3	
Classification (EC 1272/2008)	Classification (67/548/EEC)	
Acute Tox. 4 - H302	C;R35	
Skin Corr. 1A - H314	Xn;R22	

SODIUM HYDROXIDE		< 1%
CAS-No.: 1310-73-2	EC No.: 215-185-5	
Classification (EC 1272/2008) Skin Corr. 1A - H314	Classification (67/548/EEC) C;R35.	

The Full Text for all R-Phrases and Hazard Statements are Displayed in Section 16.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation

Move the exposed person to fresh air at once. Get medical attention if any discomfort continues.

Ingestion

NEVER MAKE AN UNCONSCIOUS PERSON VOMIT OR DRINK FLUIDS! Rinse mouth thoroughly. Drink plenty of water. Get medical attention if any discomfort continues.

Skin contact

Remove affected person from source of contamination. Get medical attention if irritation persists after washing.

Eye contact

Make sure to remove any contact lenses from the eyes before rinsing. Promptly wash eyes with plenty of water while lifting the eye lids. Continue to rinse for at least 15 minutes. Get medical attention if any discomfort continues.

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

Inhalation.

No specific symptoms noted.

Ingestion

No specific symptoms noted.

Skin contact

No specific symptoms noted.

Eye contact

No specific symptoms noted.

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

No recommendation given, but first aid may still be required in case of accidental exposure, inhalation or ingestion of this chemical. If in doubt, GET MEDICAL ATTENTION PROMPTLY!

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Extinguishing media

This product is not flammable. Use fire-extinguishing media appropriate for surrounding materials. Use: Water spray, fog or mist. Dry chemicals. Foam.

5.2. Special hazards arising from the substance or mixture

Specific hazards

Low hazard, liquid can burn upon heating to temperatures at or above the flashpoint.

5.3. Advice for firefighters

Special Fire Fighting Procedures

Do not enter confined fire-spaces without protective clothing and self-contained air supply.

Protective equipment for fire-fighters

Use protective equipment appropriate for surrounding materials.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Wear protective clothing as described in Section 8 of this safety data sheet.

6.2. Environmental precautions

Do not discharge into drains, water courses or onto the ground.

NOVAPLUS Surgical Instrument Lubricant

6.3. Methods and material for containment and cleaning up

Stop leak if possible without risk. Absorb in vermiculite, dry sand or earth and place into containers. Flush with plenty of water to clean spillage area. Do not contaminate water sources or sewer.

6.4. Reference to other sections

For waste disposal, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Avoid spilling, skin and eye contact.

7.2. Conditions for safe storage, including any incompatibilities

If pH exposure is below 2.5 or above 9.5 products efficacy may be lost. If temperature exceeds 130°F (55°) product efficacy may be lost. Follow GMP. Keep containers closed when not in use. Wash thoroughly after handling.

7.3. Specific end use(s)

The identified uses for this product are detailed in Section 1.2.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Name	STD	TWA - 8 Hrs		STEL - 15 Min		Notes
POTASSIUM HYDROXIDE					2 mg/m ³	
SODIUM HYDROXIDE	WEL				mg/m ³	

WEL = Workplace Exposure Limit.

Ingredient Comments

Ireland, Occupational Exposure Limits 2010

8.2. Exposure controls

Protective equipment



Engineering measures

Provide adequate general and local exhaust ventilation.

Hand protection

Use suitable protective gloves if risk of skin contact. Protective gloves complying with EN 374.

Eye protection

If risk of splashing, wear safety goggles or face shield. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Other Protection

Wear appropriate clothing to prevent any possibility of skin contact.

Hygiene measures

DO NOT SMOKE IN WORK AREA! Wash hands at the end of each work shift and before eating, smoking and using the toilet. Wash promptly if skin becomes wet or contaminated. Promptly remove any clothing that becomes contaminated. Use appropriate skin cream to prevent drying of skin. When using do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Emulsion. Colour
	Milky White
Odour	Odourless.
Solubility	Soluble in water.

NOVAPLUS Surgical Instrument Lubricant

Initial boiling point and boiling range <100 °C

Relative density 1.04±0.005

pH-Value, Conc. Solution 7±0.5

9.2. Other information

Not known.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

No specific reactivity hazards associated with this product.

10.2. Chemical stability

Stable under normal temperature conditions.

10.3. Possibility of hazardous reactions

Hazardous Polymerisation

Will not polymerise.

10.4. Conditions to avoid

Avoid excessive heat for prolonged periods of time.

10.5. Incompatible materials

Materials To Avoid

Strong acid s/oxidizers. Do not mix with chlorinated detergents (bleach).

10.6. Hazardous decomposition products

Burning may produce oxides of carbon and other substances.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Ingestion

Ingestion may causes irritation of mouth, throat and stomach with possible nausea

Skin contact

Prolonged or repeated contact with skin may cause irritation.

Eye contact

Contact with eyes may cause irritation

Health Warnings

No specific health warnings noted.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity

Not regarded as dangerous for the environment.

12.1. Toxicity

12.2. Persistence and degradability

Degradability

There are no data on the degradability of this product.

12.3. Bioaccumulative potential

Bioaccumulative potential

The product does not contain any substances expected to be bioaccumulating.

12.4. Mobility in soil

Mobility:

The product is soluble in water.

12.5. Results of PBT and vPvB assessment

12.6. Other adverse effects

None known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste and residues in accordance with local authority requirements.

SECTION 14: TRANSPORT INFORMATION

General	The product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID).
Rail Transport Notes	Not classified.
Sea Transport Notes	Not classified.
Air Transport Notes	Not classified.

14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

Transport Labels

No transport warning sign required.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Environmentally Hazardous Substance/Marine Pollutant
No.

14.6. Special precautions for user

Not applicable.

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

Not applicable.

SECTION 15: REGULATORY INFORMATION

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

Statutory Instruments

The Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (S.I 2009 No. 716).

Approved Code Of Practice

Classification and Labelling of Substances and Preparations Dangerous for Supply.

Guidance Notes

Workplace Exposure Limits EH40. Introduction to Local Exhaust Ventilation HS(G)37. CHIP for everyone HSG(108).

EU Legislation

The UN Globally Harmonised System (GHS) Safety Data Sheet format (Annex IV) is implemented as Annex II of REACH EU No 453/2010 of 20th May 2010 amending regulation (EC) No 1907/2006

15.2. Chemical Safety Assessment

SECTION 16: OTHER INFORMATION

NOVAPLUS Surgical Instrument Lubricant

Revision Date 06/03/2012
Revision 1
Risk Phrases In Full
R35 Causes severe burns.
R22 Harmful if swallowed.
NC Not classified.
Hazard Statements In Full
H314 Causes severe skin burns and eye damage.
H302 Harmful if swallowed.

HIMS Rating

Health	1	0- least 1- slight 2- moderate 3- high 4- extreme
Flammability	0	
Reactivity	0	
Personal Protection	B	

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty guarantee or representation is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.