

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.	NPL055		
1.2. Relevant identified uses of th	e substance or mixture and uses advised against		
Identified uses	Lubricate and protect moving parts and latches.		
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	Person SDS Contact: DCM Compliance, info@dcmcompliance.com		
1.4. Emergency telephone number	r		

201-313-1999

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

Classification (1999/45/EEC)

Physical and ChemicalNot classified.HazardsHuman healthNot classified.EnvironmentNot classified.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) Acute Tox. 4 - H302 Skin Corr. 1A - H314		Classification (67/548/EEC) C;R35 Xn;R22	

SODIUM HYDROXIDE

CAS-No.: 1310-73-2

EC No.: 215-185-5

Classification (EC 1272/2008) Skin Corr. 1A - H314 Classification (67/548/EEC) C;R35.

< 1%

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. <u>5.2. Special hazards arising from the substance or mixture</u>

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.

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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	
SECTION 6. EXPOSORE CONTROLS/FERSONAL PROTECTION	

8.1. Control parameters

•	Name	STD	TWA	- 8 Hrs	STEL	- 15 Min	Notes	ŀ
•	POTASSIUMHYDROXIDE	•	•	•	•	2 mg/m3	•	ŀ
	SODIUM HYDROXIDE	WEL	•	•	•	mg/m3	•]

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.

Initial boiling point and boiling	<100 °C
range	
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. <u>10.5. Incompatible materials</u>

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.

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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: TRANSP	PORT 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.
<u>14.1. UN number</u>	
Not applicable.	
14.2. UN proper shipping na	ame
Not applicable.	
<u>14.3. Transport hazard clas</u> Transport Labels	<u>s(es)</u>
	No transport warning sign required.
14.4. Packing group	
Not applicable.	
14.5. Environmental hazard	
Environmentally Hazardous No.	s Substance/Marine Pollutant
14.6. Special precautions for	<u>or user</u>
Not applicable.	
14.7. Transport in bulk acco	ording to Annex II of MARPOL73/78 and the IBC Code
Not applicable.	
SECTION 15: REGULA	TORY INFORMATION
15.1. Safety, health and env	vironmental regulations/legislation specific for the substance or mixture
Statutory Instruments	
The Chemicals (Hazard I	Information and Packaging for Supply) Regulations 2009 (S.I 2009 No. 716).
Approved Code Of Practice	
Guidance Notes	ing of Substances and Preparations Dangerous for Supply.
Workplace Exposure Lim HSG(108).	its EH40. Introduction to Local Exhaust Ventilation HS(G)37. CHIP for everyone
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 <u>15.2. Chemical Safety Assessment</u>

SECTION 16: OTHER INFORMATION

NOVAPLUS Surgical Instrument Lubricant

Revision Date	02/02/2016
Revision	В
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
Flammability	0	1- slight 2- moderate
Reactivity	0	3- high
Personal Protection	В	4- extreme

Note:

The chemical components in the formulation, while having different risk classifications, provide a safe threshold when this product is used as directed and diluted according to manufacturer's instructions.

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