

Date: 20 December 2011

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

1.1 Product identifier

GHS Product Identifier SDP - α STL Solution B Product Code SDP - α STL Solution B

Chemical Name Mixture

Trade name SDP - α STL Solution B

CAS No. Mixture
EINECS No. Mixture
REACH Registration No. Not available

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

Identified use(s)
Users are recommended to seek further advice.
Uses advised against
Users are recommended to seek further advice.

1.3 Supplier's details

Company Identification Mitsubishi Imaging (MPM), Inc.

Address 555 Theodore Fremd Avenue, Rye, NY 10580 USA

Telephone (914) 925-3200

E-Mail (competent person)

1.4 Emergency telephone number – ChemTrec

Emergency Phone No. (800) 424-9300 (US/Canada), +01 (703) 527-3887 (Elsewhere)

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture
- 2.1.1 Regulation (EC) No. 1272/2008 (CLP) Skin Irritation 2, Eye Irritation 2, Respiratory Sensitizer 1, (3.2/2, 3.3/2, 3.4/1)
- 2.1.2 Directive 67/548/EEC & Directive 1999/45/EC -Harmful
- 2.2 Label elements
- 2.2.1 Label elements According to Regulation (EC) No. 1272/2008 (CLP)

GHS Product Identifier (EU)

Hazard pictogram(s)

Signal word(s) Danger

Hazard H315 Causes skin irritation.

statement(s) H319: Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary P261 Avoid breathing mist/ vapours/ spray.

Statement(s) P281: Use personal protective equipment as required.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes.

Remove

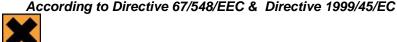
contact lenses, if present and easy to do. Continue rinsing.

P304 + P341: IF INHALED: If breathing is difficult, remove victim to fresh air and

keep at rest in a position comfortable for breathing.

2.2.2 Label elements

Hazard Symbol



Risk Phrases R36/38: Irritating to eyes and skin.

R42 May cause sensitization by inhalation.

Safety Phrases S24/25: Avoid contact with skin and eyes.

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

seek medical advice.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

2.3 Other hazards Hazardous under OSHA Hazard Communication Standard (USA)

HMIS: Health-1, Flammability- 0 Reactivity – 0 GHS Classification (USA):Irritant (Eyes, Skin).

H319: Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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P261 Avoid breathing mist/ vapours/ spray.

P281: Use personal protective equipment as required.

P304 + P341: IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

WHMIS Classification (Canada): D2A, D2B - Material causing other toxic effects. Respiratory sensitiser, Skin/Eye irritant.

H316: Causes mild skin irritation.

H319: Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray. P280 Wear protective gloves/ eye protection/ face protection.

P304 + P341: IF INHALED: If breathing is difficult, remove victim to fresh air and

keep at rest in a position comfortable for breathing.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

2.4 **Additional Information**

Potential Health Effects

Inhalation May cause irritation. May cause sensitization by inhalation.

Eye Contact Causes moderate eye irritation.

May cause irritation. Repeated or prolonged skin overexposure may cause Skin Contact

dermatitis.

Chronic ingestion exposure may have adverse effects on the kidneys and liver. Ingestion

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

EC Classification No. 1272/2008/EC

Hazardous ingredient(s)	% W /W	CAS No.	EC No.	REACH Registration No.	Hazard pictogram(s) and Hazard statement(s)	
Protease Bacillus licheniformis (Subtilisin)	3-7	9014-01-1	232-752-2	NA	3.2/2, 3.3/1, 3.4/1, 3.5/3 H315, H318, H334, H33	
1,2-Propylene Glycol	30-50	57-55-6	200-338-0	NA	None None	

EC Classification No. 67/548/EEC

Hazardous ingredient(s)	% W/W	CAS No.	EC No.	REACH Registration No.		Classification and Risk Phrases
Protease Bacillus licheniformis (Subtilisin)	3-7	9014-01-1	232-752-2	NA	×	Xn, R37/38,R41, R42
1,2-Propylene Glycol	30-50	57-55-6	200-338-0	NA	None	None

3.3 Additional Information

- For full text of H/P phrases see section 16. For full text of R phrases see section 16. Non-Hazardous ingredients are not listed and make up the balance of the product.

SECTION 4: FIRST AID MEASURES

4.1 **Description of first aid measures**

Inhalation Remove patient from exposure. Keep patient at rest and give oxygen if breathing

difficult. If symptoms develop, obtain medical attention.

Skin Wash affected skin with soap and water. If symptoms develop, obtain medical

Contact

Eye Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 15

minutes. If symptoms develop, obtain medical attention. Contact Ingestion Do not induce vomiting. Obtain immediate medical attention.

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

Acute: Liquid product is irritant to eyes and skin. Sen: Capable of

causing respiratory sensitisation

Delayed and chronic effects: Similar to acute exposures.

Indication of the immediate 4.3 medical attention and special treatment needed

Treat symptomatically.

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SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media Non-combustible.

Unsuitable Extinguishing Media None Special hazards arising from the substance or None

mixture

5.2

5.3 Advice for fire-fighters A self contained breathing apparatus and suitable protective

clothing should be worn in fire conditions.

Keep in suitable, closed containers for disposal.

Soak up with inert absorbent material and dispose accordingly.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective Ensure full personal protection (including respiratory protection) equipment and emergency procedures during removal of spillages.

6.2 Environmental precautions None

6.3 Methods and material for containment and cleaning up

6.4 Reference to other sections See Also Section 7, 8, 13.

6.5 Additional Information None

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safehandling
All employees who handle this material should be trained to handle it safely. Wear suitable protective clothing and eye/face protection. Avoid contact with eyes. Avoid

ingestion.

7.2 Conditions for safe storage, including any incompatibilities

Store at ambient termperatures. Store in a closed container. Store in a well-ventilated place. Keep/store away from: Strong acids, Strong bases and oxidizers.

Storage Temperature Ambient temperatures.
Storage Life Not available

Incompatible materials Strong oxidizing agents, Strong acids/bases.

7.3 Specific end use(s) Consult the supplier.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational Exposure Limits

SUBSTANCE	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m³)	STEL (ppm)	STEL (mg/m³)	Note:
Subtilisin *	9014-01-1	NE	NE	NE	0.00006mg/m ³	OSHA*
		NE	0.00006mg/m ³	NE	NE	ACGIH TLV*
Propylene Glycol	57-55-6	NE	NE	NE	NE	None
* Ceiling Limits for both ACGIH and OSHA values. Compliance with the subtilisins ceiling limit is assessed by sampling						

^{*} Ceiling Limits for both ACGIH and OSHA values. Compliance with the subtilisins ceiling limit is assessed by sampling with a high volume sampler (600-800 liters per minute) for at least 60 minutes.

8.1.2 Biological limit value

Biological limit value = 0.00006mg/m³ as a ceiling value for *Subtilisin* protease listed under NIOSH in the USA.

8.1.3 PNECs and DNELs

No PNECs and/or DNELs are available for this product.

8.2 Exposure controls

8.2.1 Appropriate engineering controls Guarantee sufficient ventilation during and after use, in order to prevent vapour accumulation.

8.2.2 Personal protection equipment

Eye/face protection Safety glasses.

Skin protection Plastic or synthetic rubber gloves. Wear chemical resistant apron.

Respiratory protection

Wear suitable respiratory protective equipment if exposure to levels above the occupational exposure limit is likely.

Thermal hazards None

8.2.3 Environmental Exposure Controls Adequate ventilation must be used.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Clear Liquid **Appearance** Colour Yellowish Odour Threshold (ppm) Odour Yeast like Not available Melting Point (°C) / Freezing Point (°C) Not available Boiling point/boiling range (°C): 212°F (100°C) Flash Point (°C) Not Flammable Explosive limit ranges Not available Auto Ignition Temperature (°C) Not available Decomposition Temperature (°C) Not available Explosive properties Not available Oxidising properties Not available Flammability (solid, gas) Not available pH (Value) 7.4 ± 0.2 17mm Hg @20°C Evaporation rate Vapour Pressure (mm Hg) <1 Density (g/ml) Vapour Density (Air=1) >1 1.1 ± 0.005 Solubility (Water) Complete Solubility (Other) Not available

Partition Coefficient (n-Octanol/water) Not available Viscosity (mPa.s) Like water

9.2 Other information Volatile Organic Compound (VOC) Content: 550 g / L per EPA Method 24 (does not

include water). VOC weight %: <5% (calc) per California CARB methodology.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity None

10.2 Chemical stability Stable under normal conditions.

10.3 Possibility of hazardous reactionsCan react violently if in contact with - strong acids, oxidizers.

10.4 Conditions to avoid Extreme temperatures
 10.5 Incompatible materials Strong oxidizers, strong acids

10.6 Hazardous Decomposition Product(s) Oxides of carbon, hydrocarbons, fumes, smoke.

SECTION 11: TOXICOLOGICAL INFORMATION

Ingredient	CAS No.	LD ₅₀ (Oral, Rat)	LC₅₀ (Inhalation, Rat)
Subtilisin	9014-01-1	2,000 mg/kg	No Data
Propylene Glycol	57-55-6	20.000 mg/kg	No Data

11.1 Information on toxicological effects

11.1.2 Mixtures

Acute toxicity May be harmful if swallowed..

Irritation Moderate Eye irritant, Mild skin irritant.

Corrosivity No data

Sensitisation May cause allergic respiratory reaction.

Repeated dose toxicity Persons previously sensitized may develop asthmatic symptoms.

Carcinogenicity None of the components present in this formulation at concentrations equal to or

greater than 0.1% are listed by the IARC, NTP or OSHA.

Mutagenicity Not to be expected.

Toxicity for reproduction No data

11.2 Other information None

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity No environmental hazards have been reported or known.

12.2 Persistence and degradability No data.

12.3 Bioaccumulative potential Does not bioaccumulate.

12.4Mobility in soilNo data.12.5Results of PBT and vPvB assessmentNo data.12.6Other adverse effectsNo data.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment Send to a licensed recycler, reclaimer or incinerator. Avoid release to the

methods environment.

13.2 Additional Information None

SECTION 14: TRANSPORT INFORMATION

Land transport (ADR/RID) Land transport (Within USA)

UN number Not hazardous for transport **UN** number Not hazardous for transport Proper Shipping Name Not hazardous for transport Proper Shipping Name Not hazardous for transport Transport hazard class(es) Transport hazard class(es) Not hazardous for transport Not hazardous for transport Packing Group Packing Group Not hazardous for transport Not hazardous for transport Hazard label(s) Hazard label(s) Not hazardous for transport Not hazardous for transport Environmental hazards Not hazardous for transport Environmental hazards Not hazardous for transport Special precautions for user Not hazardous for transport Special precautions for user Not hazardous for transport



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Sea transport (IMDG) Air transport (ICAO/IATA)

Not hazardous for transport **UN** number Not hazardous for transport UN number Proper Shipping Name Not hazardous for transport Proper Shipping Name Not hazardous for transport Transport hazard class(es) Not hazardous for transport Transport hazard class(es) Not hazardous for transport Packing Group Not hazardous for transport Packing Group Not hazardous for transport Marine Pollutant Not hazardous for transport Environmental hazards Not hazardous for transport Special precautions for user Not hazardous for transport Special precautions for user Not hazardous for transport

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

SECTION 15: REGULATORY INFORMATION

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

15.1.1 EU regulations

Authorisations and/or restrictions on use Consult the supplier.

European Union (EINECS/ELINCS) Referenced.

WGK number 1

15.1.2 National regulations

USA

TSCA (Toxic Substance Control Act)

SARA 311/312 - Hazard Categories

SARA 302 - Extremely Hazardous Substances

SARA 313 - Toxic Chemicals

CERCLA (Comprehensive Environmental Response

All chemicals listed

Acute Health Hazard.

Listed – None.

Listed – None.

Listed – None.

Compensation and Liability Act)

CAA (Clean Air Act 1990)

CWA (Clean Water Act)

State Right to Know Lists

Proposition 65 (California)

Listed – None.

Listed – NJ, PA

Listed – None.

Canada

WHMIS Classification Class D2A & D2B — Material causing other toxic effects.

Canada Protease Bacillus licheniformis (9014-01-1) is not listed on the Canadian DSL or NDSL. All (DSL/NDSL) other components of this product identified by CAS number are listed on the DSL or NDSL.

Canada Ingredient Disclosure List (CIDL) Listed – None

15.2 Chemical Safety Assessment: Irritant (eye/skin), sensitizer/ allergen.

SECTION 16: OTHER INFORMATION

The following sections contain revisions or new statements: 1-16. LEGEND

	American Conference of Governmental Industrial Hygienists	NA	not applicable, not available
AICS	Australian Inventory of Chemical Substances	NIOSH	National Institute for Occupational Safety and Health
ANSI	American National Standards Institute	ND	not determined
atm	atmosphere (pressure unit)	NFPA	National Fire Prevention Association
BOD	biological oxygen demand	NTP	National Toxicology Program
CAS	Chemical Abstracts Service	OC	open cup
CC	closed cup	OSHA	Occupational Safety and Health Administration
CDTA	Chemical Drug and Trafficking Act	Part	partition
COC	Cleveland Open Cup	PEL	permissible exposure limits
COD	chemical oxygen demand	ppb	parts per billion
coeff.	coefficient	PPE	personal protective equipment
CFR	Code of Federal Regulations	ppm	parts per million
CPR	cardio-pulmonary resuscitation	psi	pounds per square inch
DEA	Drug Enforcement Agency	RCRA	Resource Conservation and Recovery Act
DOT	Department of Transportation	RQ	Reportable quantity
DSCL	Dangerous Substances Classification and Labeling	RTK	Right to Know
EEC	European Economic Community	SARA	Superfund Amendments and Reauthorization Act
FDA	Food and Drug Administration	STEL	short-term exposure limit
HMIS	Hazardous Materials Information System	SUSDP	Standard for the Uniform Scheduling of Drugs and
			Poisons (Australia)
IARC	International Agency for Research on Cancer	TCC	Tagliabue Closed Cup
IDLH	immediate danger to life or health	TDG	Transportation of Dangerous Goods
kg	kilogram	TPQ	threshold planning quantity
L	liter	TQ	threshold quantity
LC50	median lethal concentration	TSCA	Toxic Substances Control Act
LD50	median lethal dose	TWA	time-weighted average
LEL	lower explosive limit	UEL	upper explosive limit
mg	milligram	WES	Workplace Exposure Standard (New Zealand)
mL	milliliter	WHMIS	Workplace Hazardous Material Information System

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References: RTECS, CAS Registry, EINECS/ESIS, Casarett & Doull's Toxicology, Goldfranks's Toxicological Emergencies, Manufacturer Information

Risk Phrases

R37/38 Irritating to respiratory system and skin.

R41 Risk of serious damage to eyes.

R42 May cause sensitization by inhalation

Hazard statement(s)

H315 Causes skin irritation.

H318 Causes serious eye damage.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H335 May cause respiratory irritation.

Training advice: None

Additional Information: Ingredient names for labeling purposes (CAS #) - Water (7732-18-5), Propylene Glycol (55-57-6), Bacillus Subtilisin (9014-01-1), Sodium Bicarbonate (144-55-8).

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