

P-21-0174

Chemical Name: [REDACTED]

CASRN: [REDACTED]

Human Health Report Status:	DATE COMPLETED
HAZARD DRAFT- Pending Review	07-21-2021
HAZARD REVIEWED	08-03-2021
RISK DRAFT- Pending review	10-03-2022
RISK QC	10-05-2022
RISK REVIEWED	10-06-2022
RISK FINAL- Uploaded	10-07-2022
UPDATE DRAFT – Pending review	
UPDATE REVIEWED	
UPDATE FINAL- Uploaded	

1 HUMAN HEALTH SUMMARY

1.1 Hazard Summary

EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties, by comparing it to a structurally analogous chemical substance for which there is information on human health hazard, and other structural information. Absorption of the new chemical substance is expected to be nil to poor through the skin when neat, poor through the skin when in solution, poor through the lungs, and good through the gastrointestinal (GI) tract based on physical/chemical properties. Absorption of the LMW fraction < 500 Da is expected to be nil to poor through the skin when neat, poor to moderate through the skin when in solution, poor through the lungs, and good through the GI tract based on physical/chemical properties. For the new chemical substance, EPA did not identify any hazards based on analogue data.

1.2 Exposure and Risk Summary

For this assessment, EPA assessed worker exposures via inhalation; dermal exposures were not assessed. Exposures to the general population were not assessed because no human health hazards were identified. Consumer exposures were not assessed because consumer uses were not identified as conditions of use.

Based on the hazard determination and available qualitative risk information, EPA did not identify risks for the new chemical substance.

1.2.1 Workers

No relevant hazards were identified for the new chemical substance; therefore, risks were not evaluated. Based on no identified hazards, risks are not expected.

1.2.2 General Population

No relevant hazards were identified for the new chemical substance; therefore, risks were not evaluated. Based on no identified hazards, risks are not expected.

1.2.3 Consumers

Risks to consumers were not evaluated because consumer uses were not identified as conditions of use.



1.3 Assumptions and Uncertainties

- There are no measured data on the new chemical substance.
- Absorption of the new chemical substance is based on physical/chemical properties.
- Metabolism is assumed to be not important based on structure. The new chemical substance is expected to hydrolyze with a half-life on the order of months; however, the hydrolysis products were not assessed for human health hazard due to the long half-life.
- Health effects and the health evaluation are based on analogue data and structure.

1.4 Potentially Useful Information

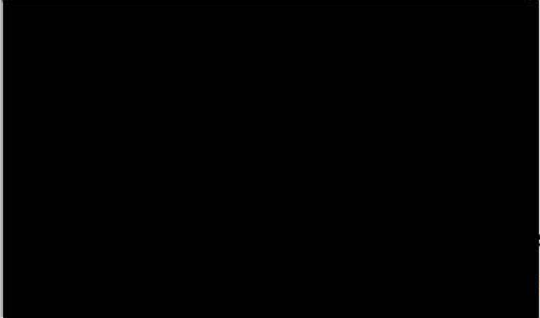



None.

1.5 Hazard Language

None.

2 HUMAN HEALTH HAZARD

2.1 Chemistry Summary

PMN:	Submitter	CRSS Date:	
P-21-0174	Marubeni America Corporation	Jul 1, 2021	
Max. PV (Kg):	Binding Option Marked:	Manu.	Import
	false		X
MW:	% <500:	% <1000:	CASNO:
Structure:	Meas.	Est.	
	MP		
	BP	>400	
	Pres.		
	VP	<0.000001	
	S-H2O	0.006/Reacts sl	
	Log P	2.79	
Chemical Name:	Analogs:	Smiles of pictured structure	
	Analogue: 		
Use:			
Intended use:			
Analogue (same use):			
Patents (same use):			

Kinematic viscosity  

2.2 Hazard Summary

2.2.1 Absorption

Absorption of the new chemical substance is expected to be nil to poor through the skin when neat, poor through the skin when in solution, poor through the lungs, and good through the GI tract based on physical/chemical properties.

Absorption of the LMW fraction < 500 Da is expected to be nil to poor through the skin when neat, poor to moderate through the skin when in solution, poor through the lungs, and good through the GI tract based on physical/chemical properties.

2.2.2 Structural Alerts

None.

2.2.3 Human Health Category (From US EPA 2010 document)

Not applicable

2.2.4 OECD QSAR Toolbox

The new chemical substance was not analyzed using the OECD QSAR Toolbox because it is outside the domain of applicability of the software.

2.2.5 Hazard Meeting Summary

No concerns were identified for the new chemical substance. This is supported by test data for a close analogue, [REDACTED], which showed no adverse effects up to and including the highest dose of 1000 mg/kg/day in a 28-day oral toxicity study in rats.

2.3 Toxicity Data

2.3.1 New Chemical Substance Data

None.

2.3.2 Analogue/Metabolite Data

2.3.2.1 [REDACTED]

Analogue

Submitted Test Data:

- Test Guideline Not Specified (Ames test): Negative in Salmonella and E. coli with and without activation
- Test Guideline Not Specified (Chromosomal aberrations test): Negative in CHL cells with and without activation
- OECD 407 (Repeated Dose 28-day Oral Toxicity Study in Rodents): Repeated Dose 28-day Oral Toxicity Study in Rodents- Groups of 5 female and 5 male CrCD(SD) rats (age 5 weeks; weight ~150 g males and ~135 g females on day 1) were exposed to 0, 25, 150, or 1000 mg/kg/day for 28 days. Recovery groups (5/sex) were also set for the 1,000 mg/kg and vehicle control groups to investigate the reversibility of the effects 14 days after the final exposure. No mortality or adverse effects were noted. No abnormalities were found in the recovery groups. Based on these results, the No-Observed-Effect Level (NOEL) was considered to be 1,000 mg/kg/day.

2.3.3 SDS Data

The SDS is relevant to the new chemical substance. The trade names are identical.

2. HAZARDS IDENTIFICATION

GHS Classification:	Explosives	Not classified
	Flammable gases	Not applicable
	Flammable aerosols	Not applicable
	Oxidizing gases	Not applicable
	Gases under pressure	Not applicable
	Flammable liquids	Not classified
	Flammable solids	Not applicable
	Self-reactive substances and mixtures	Classification not possible
	Pyrophoric liquids	Classification not possible
	Pyrophoric solids	Not applicable
	Self-heating substances and mixtures	Classification not possible
	Substances and mixtures, which in contact with water, emit flammable fumes	Classification not possible
	Oxidizing liquids	Classification not possible
	Oxidizing solids	Not applicable
	Organic peroxides	Classification not possible
	Corrosive to metals	Classification not possible
	Acute toxicity (oral)	Classification not possible
	Acute toxicity (dermal)	Classification not possible
	Acute toxicity (inhalation:gas)	Not applicable
	Acute toxicity (inhalation: vapour)	Classification not possible

Acute toxicity (inhalation:dust, mist)	Classification not possible
Skin corrosion / irritation	Classification not possible
Serious eye damage / eye irritation	Classification not possible
Respiratory sensitizer	Classification not possible
Skin sensitizer	Classification not possible
Germ cell mutagenicity	Classification not possible
Carcinogenicity	Classification not possible
Toxic to reproduction	Classification not possible
Specific target organs/systemic toxicity following single exposure	Classification not possible
Specific target organs/systemic toxicity following repeated exposure	Classification not possible
Aspiration hazard	Classification not possible

SYMBOL:

Not applicable

SIGNAL WORD:

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3. COMPOSITION / INFORMATION ON INGREDIENTS

SUBSTANCE/MIXTURE: Substance
CHEMICAL NAME: [REDACTED]
CONTENT: ≥ 99%
CAS No.: Not disclosed
EINECS NO.: Not applicable (Polymer)
UN CLASS: Not applicable
UN No.: Not applicable

11. TOXICOLOGICAL INFORMATION

Not available

2.3.4 Other Information

- NAVG MW = [REDACTED] with [REDACTED]% < 500 and [REDACTED]% < 1000 (PMN submission). The GPC attachment reports a NAVG MW of [REDACTED] with [REDACTED] < 500 and [REDACTED] < 1000.
- A biodegradability test demonstrated that the new chemical substance reacts with water slowly to release [REDACTED]. Over a timespan of 28 days, 27% disappearance rate of the new chemical substance in water was measured and [REDACTED] were detected as hydrolysis byproducts. The new chemical substance is expected to hydrolyze with a half-life of months to give [REDACTED].



2.4 Exposure Routes of Interest

Route of Interest	
	Inhalation: No systemic effects expected.
	Dermal: No systemic effects expected.
	Ingestion: No systemic effects expected.

2.5 Point of Departure (POD) Selected and Basis

No quantitative POD was identified for systemic effects for any route of exposure because no systemic effects were identified for the new chemical substance.

3 HUMAN HEALTH RISK

3.1 USES and EXPOSURES

3.1.1 Uses

Intended use: Chemical intermediate for polyurethane which will be used for [REDACTED]

3.1.2 Worker Exposure

Per Engineering Report dated 08-05-2021

3.1.2.1 Inhalation

USE: Chemical Intermediate

Negligible (VP < 0.001 torr); no mist/aerosol generation expected

3.1.2.2 Dermal

USE: Chemical Intermediate

Dermal exposures were not assessed

3.1.3 General Population Exposure

Per Exposure Report dated 08-09-2021

Exposure Scenario ¹	Water					Landfill	Stack Air		Fugitive Air			
	Drinking Water		Fish Ingestion		7Q10 ⁴ CC = 200		PDM Days Exceeded	LADD	ADR (24-hr conc.)	LADD (Annual conc.)	ADR (24-hr conc.)	LADD (Annual conc.)
	ADR	LADD	ADR	LADD								
USE:Max ADR: max acute eco	--	--	--	--	6.38e+1	--	--	--	--	--	--	--
USE:PDM	--	--	--	--	6.38e+1	0	--	--	--	--	--	--

3.1.3.1 Drinking Water

Oral hazards are not identified; therefore, drinking water exposures were not evaluated.

3.1.3.2 Fish Ingestion

Oral hazards are not identified; therefore, fish ingestion exposures were not evaluated.

3.1.3.3 Landfill

Oral hazards are not identified; therefore, exposures to groundwater impacted via landfill leachate were not evaluated.

3.1.3.4 Air/Inhalation

Stack: Inhalation hazards are not identified; therefore, stack air exposures were not evaluated.

Fugitive: Inhalation hazards are not identified; therefore, fugitive air exposures were not evaluated.



3.1.4 Consumer Exposure

No identified consumer exposures

3.2 RISK CALCULATIONS

3.2.1 Worker Calculations

No relevant hazards were identified for the new chemical substance; therefore, risks were not evaluated. Based on no identified hazards, risks are not expected.

3.2.2 General Population Calculations

No relevant hazards were identified for the new chemical substance; therefore, risks were not evaluated. Based on no identified hazards, risks are not expected.

3.2.3 Consumer Calculations

Risks to consumers were not evaluated because consumer uses were not identified as conditions of use.