

GLOBAL PRODUCT STRATEGY SAFETY SUMMARY

AMPHITOL 55AB

This document is a high-level summary provides usage of chemical substances and safety information to the general public. It is not intended to replace the Safety Data Sheet, which is available from suppliers and should be referred to for full details of recommended safety procedures for each type of use. It is not intended to replace or supersede manufacturer's instructions and warnings for their consumer products containing this substance.

1. Substance Identity

Brand Name: AMPHITOL 55AB

Chemical Name: Cocamide propyl betaine (main component)

CAS Number: 61789-40-0 (main component)

2. Uses and Applications

AMPHITOL 55AB is an amphoteric surfactant. It is used as a foam solubilizer for quasi - drugs and cosmetics.

3. Physical/Chemical Properties

AMPHITOL 55AB has no identified physicochemical hazards.

Property	Value
Physical state	Liquid
Colour	Light yellow clear
Odour	Slightly characteristic odour
pH	7 (1% solution)
Density	1.058 g/mL(77 °F)(25°C) 1.056 g/mL(86 °F) (30°C)

	1.051 g/mL(104 °F) (40°C)
Freezing point	<20 °C (<68 °F)
Boiling point	No information available
Flash point	No information available
Flammability	No information available
Explosive properties	No information available
Self – ignition temperature	No information available
Vapour pressure	No information available
Water solubility	Soluble
Octanol-water partition coefficient (log K _{ow})	No information available
Viscosity	13 mPa·s (25 °C) (77 °F) 12.2 mPa·s (30 °C) (86 °F) 11 mPa·s (40 °C) (104 °F)

4. Human Health Safety Assessment

Consumer: The exposure to AMPHITOL 55AB is at safe levels.

Worker: The repeated exposure of AMPHITOL 55AB does not cause any toxic effects.

Effect Assessment	Result
Acute Toxicity oral/ dermal	No acute toxicity after oral/ dermal exposure in practical use. The substance does not cause damage to any organs following single exposure.
Irritation skin/ eye	Based on the available data, unlikely to cause skin irritation. Undiluted substance causes serious eye damage.
Sensitization	Based on the available data, unlikely to cause allergic skin reaction.
Toxicity after repeated exposure	Unlikely to cause any toxic effects through prolonged or repeated oral exposure in practical use.
Mutagenicity	Based on the available data, unlikely to cause genetic defects.
Carcinogenicity	Based on the available data, unlikely to cause cancer.
Toxicity for reproduction	Based on the available data, unlikely to be damaging to fertility or the unborn child.

5. Environmental Safety Assessment

The test results with fish, aquatic invertebrates and algae suggest that AMPHITOL 55AB could cause a toxicity to aquatic organisms. It also could cause harmfulness to aquatic organisms with long lasting effects. However, AMPHITOL 55AB is unlikely to persist in the environment

because of showing the readily biodegradation. AMPHITOL 55AB does not bioaccumulate in the food chain.

Effect Assessment	Result
Aquatic Toxicity	Based on the available data, likely to cause a toxicity to aquatic organisms and harmful to aquatic life with long lasting effects
Biodegradation	Readily biodegradable
PBT/ vPvB conclusion	Not persistent in the environment, not bioaccumulating in organisms and not toxic nor very persistent and very bioaccumulating

6. Exposure

Consumer

The consumer can come into contact with the substance in use of the quasi-drugs and cosmetic products, but the concentration of AMPHITOL 55AB in use is below the level which would give rise harmful effects of concern. When it's used as the recommended use, consumer should always read product information before use and follow the label/ use instructions.

Worker

The exposure can occur either in AMPHITOL 55AB manufacturing facilities or in the various industrial facilities when AMPHITOL 55AB is used. Those workers in industrial operations during maintenance, sampling, testing, or other procedures could be exposed with AMPHITOL 55AB. Only qualified and trained workers handle the undiluted substance. The manufacturing facilities offer thorough training program for employees and appropriate work processes, as well as safety equipment (goggles and gloves) in place to prevent an unnecessary exposure. Safety showers and eye-wash stations are accessible nearby. Workers are required to be trained in accordance with the safety measures in the Safety Data Sheet.

Environment

Since this substance is used extensively, it is discharged to waste water treatment plants from industrial sites such as manufacturing, preparation, handling, storage and use of the substance as well as from consumer households. However, the substance is readily biodegradable, so that it is removed efficiently in waste water treatment plants. The substance is biologically degraded in the surface water and is rapidly removed even if it is remained slightly in the waste water. Hence, the chronic exposure to aquatic organisms of the substance is unlikely to occur. Furthermore, the substance does not accumulate in the food chain, so that there is no concern of human exposure through environmental pathway.

7. Risk management recommendations

When you use the substance, make sure to be measured the adequate ventilation. Always use appropriate chemical-resistant gloves to protect your hands and skin and always wear

eye protection equipment. Do not eat, drink or smoke where the substance is handled, processed or stored. Wash hands and skin after contact with the substance. When the substance attaches to skin (or hair), take off the contaminated clothes. Wash with a large amount of water and soap. If the substance gets into your eyes, rinse your eyes thoroughly for several minutes. If you wear contact lens, and you can take it off easily, take it off and continue to rinse your eyes. When it causes your skin irritation or eye irritation, consult doctor (medical diagnosis/therapy).

Waste water containing the substance must be passed the waste water treatment plants in order to remove the substance. No specific measures are needed, because it is not expected to be released into the air.

8. Regulatory Information / Classification and Labelling

Under GHS classification chemical substances are classified in hazards for physical properties, human health and environment. The hazard information for industrial products are transmitted via specific labels and Safety Data Sheet. GHS offers the standardization for hazard communication. The subjects who could be assumed to be exposed to the substance, workers, consumers, transport workers, and emergency responders, can better understand the hazards of the chemicals in use through the transmission.

Labeling according to UN GHS

UN GHS is the basis for country specific GHS labeling.

ANHITOL 55AB may be assigned to following GHS classification.



Classification and Labeling Information

Eye Damage 1

Aquatic Acute 2

Aquatic Chronic 3

Hazard Statements:

H319: Causes serious eye irritation

H401: Toxic to aquatic life

H412: Harmful to aquatic life with long lasting effects

Signal Word

Danger

The laws of manufacturing, sale, transport, use and disposal are different among countries or areas. Details are referred to Safety Data Sheet provided by the supplier.

9. Conclusion

AMPHITOL 55AB could cause a toxicity to aquatic organisms. It also could cause harmfulness to aquatic organisms with long lasting effects. However, AMPHITOL 55AB is unlikely to persist in the environment because of showing the readily biodegradation. In the PBT/vPvB assessments for AMPHITOL 55AB, the substance is not applicable to PBT/vPvB. When handling the substance, workers should follow the standard safety measures and refer to the Safety Data Sheet. Consumers will usually not come into contact with the substance bulk and the substance is used diluted products, therefore, it is considered that AMPHITOL 55AB gives rise no hazardous effects to human health.

10. Contact information within company

For further information on this substance or product safety summaries in general, please contact:

Name	Kao Corporation, Global Chemical Business
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Additional information can be found at a chemical risk assessment support portal provided by the Japan Chemical Industry Associations, found at <https://www.jcia-bigdr.jp/jcia-bigdr/en/top>.

11. Glossary

Acute Toxicity	Adverse effects that result from a single exposure
Sensitization	Inducibility of allergy
Genotoxicity	Effects to induce gene mutations
Carcinogenicity	Action influence to cause a cancer
Toxicity for Reproduction	Adverse effects for teratogenicity, embryotoxicity, and reproductivity
Biodegradation	Biological degradation of a substance in environments
PBT (Persistent, Bioaccumulative and Toxic)	Substances that are environmentally persistent, bioaccumulative, and toxic
vPvB (Very Persistent and Very Bioaccumulative)	Substances with high persistence in the environment and high accumulation in ecology
GHS	Globally Harmonized System of Classification and Labelling of Chemicals

12. Date of issue

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