

GLOBAL PRODUCT STRATEGY SAFETY SUMMARY

AMPHITOL 20HD

This document is a high-level summary intended to provide the general public with an overview of product safety for this substance. 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 20HD

Chemical Name: 1-Dodecanaminium, N-(2-hydroxy-3-sulfopropyl)-N,N-dimethyl-, inner salt
(Main component)

CAS Number: 13197-76-7 (Main component)

2. Uses and Applications

AMPHITOL 20HD is an amphoteric surfactant. It is used in a detergent and body cleansing agent and others.

For the industrial use, AMPHITOL 20HD is mainly used as emulsifier, and others.

3. Physical/Chemical Properties

AMPHITOL 20HD has no identified physicochemical hazards.

Property	Value
Physical state	Liquid
Colour	Light yellow clear

Odour	Characteristic odour
pH	6 – 8 (1% solution)
Density	1.108 g/mL (25°C) (77°F), 1.098 g/mL (40°C) (104°F), 1.087 g/mL (60°C) (140°F)
Melting point	-10.5°C (13.1°F)
Boiling point	No information available
Flash point	Not applicable
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	29 mPa.s (25°C) (77°F), 24 mPa.s (40°C) (104°F), 19.5 mPa.s (60°C) (140°F)

4. Human Health Safety Assessment

Consumer: The exposure to AMPHITOL 20HD is at safe levels.

Worker: The repeated exposure of AMPHITOL 20HD 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	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 20HD could cause a harmful effect to aquatic organisms. However, AMPHITOL 20HD is unlikely to persist in the environment because of showing the readily biodegradation. AMPHITOL 20HD is unlikely to cause bioaccumulation by the food chain, because AMPHITOL 20HD is not PBT/ vPvB.

Effect Assessment	Result
Aquatic Toxicity	Based on the available data, likely to cause a harmful effect for aquatic organisms
Biodegradation	Readily biodegradable
PBT/ vPvB conclusion*	Not persistent in the environment, not bioaccumulating in organisms and not toxic nor very persistent and very bioaccumulating

*PBT=Persistent, Bioaccumulative and Toxic
vPvB=Very Persistent and Very Bioaccumulative

6. Exposure

Consumer

The consumer can come into contact with the substance in use of the detergent, the body cleansing agent and others, but the concentration of AMPHITOL 20HD 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 20HD manufacturing facilities or in the various industrial facilities when AMPHITOL 20HD is used. Those workers in industrial operations during maintenance, sampling, testing, or other procedures could be exposed with AMPHITOL 20HD. 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 present 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 even if it 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 by the food chain, and there is no concern to human health by the exposure of the substance through environmental pathway.

7. Risk management recommendations

When you use the substance, make sure to be measured the adequate ventilation. Always wear appropriate 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. Wash hands and skin with a large amounts of water and soap, when the substance attaches to skin (or hair). 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. Contact to a doctor immediately.

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.

AMPHITOL 20HD may be assigned to following GHS classification.



Classification and Labeling Information

Eye Dam. 2A

Aquatic Acute 3

Hazard Statements:

H318: Causes serious eye irritation

H402: Harmful to aquatic life

Signal Word

Warning

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

Though AMPHITOL 20HD is suggested to cause a harmful effect to aquatic organisms, there is no concern to the environmental organisms due to the rapid biodegradation of AMPHITOL 20HD. In the PBT/vPvB assessments for AMPHITOL 20HD, the substance is not PBT/vPvB. Contact with the undiluted AMPHITOL 20HD may cause serious irritation to the eyes. 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 20HD 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:

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Additional information can be found at the International Council of Chemical Associations portal, found at <http://www.icca-chem.org/en/Home/ICCA-initiatives/global-product-strategy/>.

11. Glossary

Acute Toxicity	Adverse effects that result from a single exposure
Biodegradation	Biological degradation of a substance in environments
Bioaccumulation	Accumulation of substances in environments
Carcinogenicity	Action influence to cause a cancer
Toxicity after repeated exposure	Adverse effects that result from repeated exposure
GHS	Globally Harmonized System of Classification and Labeling of Chemicals
Hazard	Hazardous property for human health or environments
Mutagenicity	Effects to induce gene mutations
Toxicity for reproduction	Adverse effects for teratogenicity, embryotoxicity, and reproductivity
Sensitization	Inducibility of allergy

12. Date of issue

19 Dec. 2016