SHIPPING RECOMMENDATIONS FOR SELECT AGENT TOXINS

Sarah A. Ziegler, Ph.D. Paul J. Meechan, Deborah E. Wilson DrPH

How do I ship my select agent toxin?

Division 6.1, but which packing group?



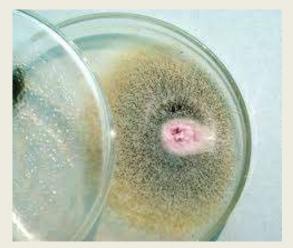


Select Agent Toxins

| Toxin | Amounts |
|--|---------|
| Abrin | 100mg |
| Botulinum neurotoxins | 0.5mg |
| α-Conotoxins (short, paralytic) | 100mg |
| Diacetoxyscirpenol (DAS) | 1000mg |
| Ricin | 100mg |
| Saxitoxin | 100mg |
| Staphylococcal Enterotoxins (Subtypes A,B, C, D and E) | 5mg |
| T-2 toxin | 1000mg |
| Tetrodotoxin | 100mg |







Division 6.1 Packing Groups UN 3462

Packing Group I

- Forbidden on passenger aircraft
- FedEx does not accept
- Are not permitted under the Limited Quantities provision

Packing Group II Allowed on passenger aircraft

FedEx does not accept

Packing Group III

- Accepted by FedEx
- Must have PGIII label







Packing Group Determination

Assignment of packing group for Division 6.1 solid materials. Adapted from 49 CFR 173.133 and 173.132

| | Oral toxicity | | Inhalation toxicity by |
|---------|--------------------------|----------------------------------|-------------------------|
| | LD ₅₀ (mg/kg) | Dermal toxicity LD ₅₀ | dusts and mists |
| | As determined in | (mg/kg) | LC ₅₀ (mg/L) |
| Packing | young adult albino | As determined in albino | As determined in |
| group | rats | rabbits | young adult albino rats |
| I | ≤5.0 | ≤50 | ≤0.2 |
| II | >5.0 and ≤50 | >50 and ≤200 | >0.2 and ≤2.0 |
| III | >50 and ≤300 | >200 and ≤1000 | >2.0 and ≤4.0 |





What packing group for the Select Agent Toxins?

Packing Group I

Packing Group II

Packing Group III

Information that Disagrees

Abrin (NIOSH)

Hazardous Materials Warning Labels/Placards

- Shipping Name: Toxins, extracted from living sources, solid, n.o.s.
- Identification Number: 3462 (Guide 153)
- Hazardous Class or Division: 6.1
- · Subsidiary Hazardous Class or Division:
- Label: Poison (Toxic) PG III
- Placard Image:



Ricin (NIOSH)

Hazardous Materials Warning Labels/Placards

- Shipping Name: Toxins, extracted from living sources, solid, n.o.s.
- Identification Number: 3462 (Guide 153)
- Hazardous Class or Division: 6.1
- · Subsidiary Hazardous Class or Division:
- Label: Poison (Toxic) PG III
- · Placard Image:



Information that Disagrees

SEB

14. TRANSPORT INFORMATION

IATA

Product #122

UN number: UN3462 Class: 6.1 Packing group: I

Proper shipping name: Staphylococcus aureus

Tetrodotxin

14.3 AIR TRANSPORT (ICAO/IATA):

ICAO/IATA Shipping Name: Toxins, extracted from living sources, solid, n.o.s. (Tetrodotoxin Citrate)

UN Number: 3462 Packing Group: 1

Hazard Class: 6.1 - POISON IATA Classification: 6.1

Additional Transport Transport in accordance with local, state, and federal regulations.

Information: When sold in quantities of less than or equal to 1 mL, or 1 g, with an Excepted Quantity

Code of E1, E2, E4, or E5, this item meets the De Minimis Quantities exemption, per

IATA 2.6.10. Therefore packaging does not have to be labeled as Dangerous

Goods/Excepted Quantity.

Why does this matter?

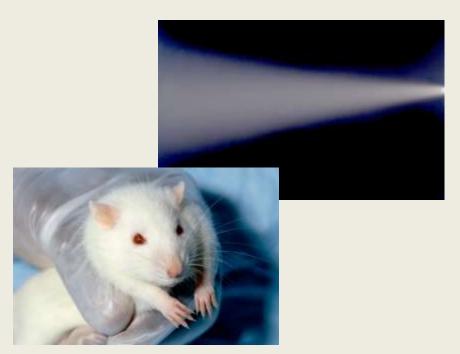
- Uniformity of shipping of regulated and hazardous material
- Decreased shipping costs for downgraded items
- Items shipped incorrectly pose a risk







Misalignment of published data with IATA guidelines









Determination using data

| Ricin | | | |
|---|--------------|--------------|--|
| Published LD ₅₀ values | Route | Animal model | |
| no dermal toxicity was observed at 50-µg | Dermal | Mouse | |
| 0.003 to 0.005 mg/kg | inhalation | Mouse | |
| 20 mg/kg | intragastric | Mouse | |
| 0.002 mg/kg | IP | Mouse | |
| 0.022 mg/kg | IP | Mouse | |
| 0.0027mg/kg | IV | Mouse | |
| 0.005 mg/kg | IV | Mouse | |
| 0.003 mg/kg | IV | Mouse | |
| 0.024 mg/kg | SQ | Mouse | |
| 0.00012mg/L over 50 minutes was 100% lethal | ?? | Rats | |

Determination using data

| T-2 | | |
|-----------------------------------|-------|--------------|
| Published LD ₅₀ values | Route | Animal model |
| 3 mg/kg | IP | Mouse |
| 1.2 mg/kg | IV | Mouse |

When all else fails, pick up the phone and ask for help.



Compiled Data

| | LD ₅₀ values (per kg) | | |
|-----------------------------|----------------------------------|----------------------------------|--------------------|
| Toxin | IV or IP | Ingestion | Inhalation |
| Abrin | 700 ng (mice) | 0.1-1 ug (human) | |
| Botulinum neurotoxins | 0.4-2.5 ng (mice) | | 0.01 ug (human) |
| Conotoxins | 5.0 mg (mice), 1.45 mg (mice) | | |
| Diacetoxyscirpenol | | 2140 ug (guinea pig) | 11.3 mg (mouse) |
| Ricin | 2.7 ug (mice) | | 0.24 ug (rat) |
| Saxitoxin | | 263 ug (mice), ~15 ug (human) | |
| Staphylococcal enterotoxins | | ~14 ug (human) | |
| T-2 toxin | | 5-10 mg (rodent) | 35 ug (rodent) |
| Tetrodotoxin | | ~15 ug (human) | 2 ug (human) |

Proposed Guidance

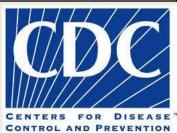
| | LD50 values (per kg) | | Recommended |
|-----------------------------|----------------------|--------------------|---------------|
| Toxin | Ingestion | Inhalation | Packing Group |
| Abrin | 0.1-1 ug (human) | | I |
| Botulinum neurotoxins | | 0.01 ug (human) | I |
| Conotoxins | | Est 15-50mg (mice) | II |
| Diacetoxyscirpenol | 2140 ug (guinea pig) | 11.3 mg (mouse) | II |
| Ricin | | 0.24 ug (rat) | I |
| Saxitoxin | 263 ug (mice) | | I |
| Staphylococcal enterotoxins | ~14 ug (human) | | 1 |
| T-2 toxin | 5-10 mg (rodent) | 35 ug (rodent) | I |
| Tetrodotoxin | ~15 ug (human) | 2 ug (human) | I |

| IATA Guidelines | | | |
|-----------------|-------------------------|------------------|--|
| PGI | <5.0 mg/kg | <0.2 mg/kg | |
| PGII | 5.0 to 50 mg/kg | 0.2 to 2.0 mg/kg | |
| PGIII | 50 to 300 mg/kg | 2 to 4 mg/kg | |
| | young adult albino | | |
| Animal Model | young adult albino rats | rats | |

Where do we stand now?

| Toxin | Recommended Packing Group |
|-----------------------------|---------------------------|
| Abrin | I |
| Botulinum neurotoxins | I |
| Conotoxins | II |
| Diacetoxyscirpenol | II |
| Ricin | I |
| Saxitoxin | I |
| Staphylococcal enterotoxins | I |
| T-2 toxin | I |
| Tetrodotoxin | I |





Moving Forward

- Publication of the Guidelines with DOT and DSAT
- NIOSH recommendations

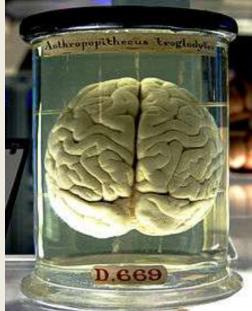


Wisdom gained

- Even though you think guidance or data should be there, its not always available
- Bureaucracy can be quick and easy

Other times bureaucracy can be very

slow



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